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Silver-Impregnated Dressings and Pediatric Care

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Personalized medicine, the “careful matching of your biology to your medical care,”1 holds great promise for improving patient outcomes. All health professions can apply the principles of personalized medicine within their own disciplines, and personalized approaches should drive interdisciplinary care. Neither personalized medicine nor the broader concept of personalized care delivered by the interdisciplinary team have been widely applied to critically ill patients. The lack of personalized care may seem counterintuitive, since the care of critically ill patients is highly individualized. Although critical care clinicians usually do not know the patient prior to hospitalization, they quickly acquaint themselves with the problems that brought the patient to the intensive care unit (ICU) and with the preexisting diseases that may impact their care and clinical course. Families are involved, and patient and family wishes regarding care are explored. So how does personalized care differ from the individualized patient-centered care we currently provide, and why is personalized care so vital to improving outcomes for critically ill patients?

Beyond Current Care Practices
Whereas these aspects of individualized care are important, personalized care requires going beyond our current practices to understand and predict the effects of therapies based on each patient’s distinctive characteristics so that clinicians and families can make more informed choices about care. Personalized care must be grounded in evidence, and depends on high-quality research about how patient characteristics influence risks, responses to interventions, and prognosis. Individualized care is reactive, starting from generic interventions and adapting as needed; personalized care is proactive, starting from the uniqueness of the patient.

Discussions of personalized care often center on the use of genetic or genomic information in decision
making related to prescribing medications. In cases where the relationships among genes and drug response have been elucidated, the initial choice of drug and dose can be tailored to a patient’s genetic makeup to maximize therapeutic benefit and reduce the risk of untoward effects.

Pharmacogenomic information has already begun to influence prescribing decisions, particularly in oncology and cardiology, but has not yet had a significant impact on critical care practice. However, use of genetic/genomic profiles to understand risks and guide treatment is not limited to pharmacogenomics. In an elegant research report this year, Davenport and colleagues found that expression of 7 genes could be used to classify ICU patients on admission with sepsis into 2 distinct “sepsis response signature” groups. The 2 groups differed in immune responses and in mortality, even though the 2 groups could not be distinguished by clinical characteristics. The authors propose that sepsis response signatures could identify high risk patients, permit development of novel personalized interventions, and improve our understanding of sepsis pathophysiology. Gene expression investigation will likely yield important knowledge about other aspects of critical illness.

More broadly, personalized care involves consideration not only of genetic/genomic information but of other biologically relevant variables as well. Biologically relevant variables such as sex, age, and body mass index are important factors in patient outcomes, but how these variables should be used to personalize care has not been well studied in critical care research. The National Institutes of Health and the Agency for Healthcare Research and Quality recently have issued new regulations for research to increase scientific rigor and transparency and to enhance the reproducibility of research findings. The new guidance requires that investigators account for biologically relevant variables in study design and analysis, and specifically calls out sex as a biologically relevant variable to be considered.

Clinical research routinely presents demographic information that includes biologically relevant variables; however, the data are usually presented to describe the sample rather than being included in the analytic strategies. When biologically relevant variables are presented as sample descriptors, we can judge how representative the sample is of the population (for example, the balance of men and women), but these descriptive data offer little guidance that would provide direction for personalized care.

**New Research Is Imperative**

It is imperative that critical care research move forward with understanding how biologically relevant variables affect care, and we must act on that knowledge. Biologically relevant variables may affect risk, and are important in targeting surveillance and prevention efforts to greatest patient benefit. For example, a recent meta-analysis found that advancing age is a strong risk factor for ICU delirium, and this information has shaped targeted delirium prevention protocols.

Biologically relevant variables may affect prognosis. In a recent national cohort study analysis of long-term survivors of sepsis following cardiopulmonary resuscitation, both male sex and advancing age were significant predictors of mortality. Biologically relevant variables may direct personalized interventions at the bedside in the same way that genetic/genomic data have begun to direct pharmacologic interventions. Research to expand our knowledge about personalized care will enable critical care clinicians to align patients who are most likely to benefit from receiving an intervention to delivery of that intervention at a particular point in time or in a particular way.

**Challenges and Potentials**

Personalized care will present challenges. Research studies may require increased sample sizes to have adequate statistical power necessary for examination of biologically relevant variables. It may require larger multisite studies with associated logistic and funding issues. Importantly, each individual is a unique expression of a multitude of characteristics, and models of personalized care will only be able to accommodate a finite set of those variables.

In the future, whole genome sequencing may become routine and genetic/genomic data will be readily available as part of the medical record. Until
In the future, whole genome sequencing may become routine.

that time, access to genetic/genomic data for decision making in critical care will be limited, and we will continue to infer genetic risks from family history. Clinical decision support systems that could assist in making sense of a larger set of personalized data, including genetic/genomic data, are still in their infancy and beset with hurdles related to implementation and provider acceptance.7

A New World of Patient Care

Our patients will benefit when we develop a deeper understanding about how their personal characteristics affect their care. Critical care practice will improve as a result of a systematic application of that understanding to optimize outcomes for each patient. The best approaches will maintain individualized care, which is grounded in physical functioning, psychosocial and spiritual well-being, and patient values and preferences, while at the same time incorporating the exciting, innovative potential of personalized care, which is grounded in each patient’s unique biological characteristics and individual variation.

The statements and opinions contained in this editorial are solely those of the coeditors in chief.

FINANCIAL DISCLOSURES
None reported.
Clinical Pearls

Rhonda Board, RN, PhD, CCRN, Section Editor

Clinical Pearls is designed to help implement evidence-based care at the bedside by summarizing some of the most clinically useful material from select articles in each issue. Readers are encouraged to photocopy this ready-to-post page and share it with colleagues. Please be advised, however, that any substantive change in patient care protocols should be carefully reviewed and approved by the policy-setting authorities at your institution.

Family Participation in Intensive Care Unit Rounds and Telemedicine

One way to increase family participation is through purposeful interactions in family-centered rounds. Stelson and colleagues interviewed family members and adult surgical intensive care unit (ICU) providers to examine their perspectives on family participation in rounds and the role of telemedicine as a communication tool. They found the following:

- Significant differences existed between the 2 groups on structure, style, and purpose of rounds.
- Both groups identified facilitators to communication such as familiarity with medical concepts and desire to understand prognosis, as well as barriers such as family members not wanting to be “bothersome.”
- Both groups described 2 benefits to the use of telemedicine: convenience and interpersonal advantages. However, user-friendly and reliable platforms would be required.

The authors note that communication is the key to family satisfaction with ICU care and that telemedicine platforms be explored as a feasible means of family participation.

See Article, pp e98-e107

Nurses and Environmental Change

Critically ill children are exposed to a multitude of factors that affect sleep, sedation needs, and physiological parameters such as heart rate and respiratory rate. This noisy environment can also contribute to nurses’ stress and decreased work satisfaction. Kudchadkar and colleagues examined the perceptions of pediatric intensive care unit (PICU) nurses about the PICU environment after transitioning from a unit with multipatient rooms to a unit with single-patient rooms. They found the following:

- Single-patient room layout was more conducive to patients sleeping at night and promoting normal sleep-wake cycles.
- Nurses perceived less stress and more environmental control in the all-private room layout.
- Monitors/alarms and staff conversations still negatively affected noise levels in single-patient rooms.

Although PICU architectural design was shown to have a positive impact on both patient health and nursing staff perceptions of work, the authors also recommend quality improvement initiatives to individualize alarm thresholds to reduce alarm fatigue.

See Article, pp 440-447

In Situ Mock Code for Quality Improvement

Higher survival rates from cardiac arrest are associated with quick administration of cardiopulmonary resuscitation. Yet knowledge and hands-on skills learned from basic and advanced life support are quickly lost after program completion, contributing to anxiety and poor performance in medical emergencies. In settings with high risk and low volume of medical emergencies, this loss can put patients at risk for adverse outcomes. Herbers and Heaser implemented an in situ (realistic setting) simulation mock code program to increase nursing performance and confidence levels during medical emergencies. Quarterly mock codes were conducted over 2 years and the results showed the following:

- Response time calling for help improved 11%, time to initiate chest compressions improved 28%, and timing of initial defibrillation improved 20%.
- Nursing staff levels of overall confidence in code situations improved from 86.5% before to 98.8% after.

The authors suggest use of in situ mock codes as a quick and efficient way to give hands-on practice in a team-centered approach.

See Article, pp 393-399

Decreasing Prolonged Ventilation in CABG

The number of coronary artery bypass graft (CABG) surgeries has risen, resulting in increased costs. The American College of Cardiology 2011 guideline recommends use of anesthetics that support early extubation in order to decrease hospital length of stay and health care resources. Hefner and colleagues conducted a quality improvement (QI) study to reduce the rate of prolonged mechanical ventilation and assess the sustainability of that reduction. They identified 3 interventions to address gaps between current practice and best practices:

- Development of a standardized extubation protocol
- Installation of dry erase communication boards in each patient room
- Revisions to the electronic medical record postoperative order set

After rigorous staff education over 6 months, there was a significant reduction in the rate of prolonged ventilation that was sustained 4 years postintervention. The authors credit engagement of a multidisciplinary task force and repeated protocol education to the success of this QI project.

See Article, pp 423-430

©2016 American Association of Critical-Care Nurses, doi: http://dx.doi.org/10.4037/ajcc2016330
Background The architectural design of the pediatric intensive care unit may play a major role in optimizing the environment to promote patients’ sleep while improving stress levels and the work experience of critical care nurses.

Objectives To examine changes in nurses’ perceptions of the environment of a pediatric critical care unit for promotion of patients’ sleep and the nurses’ work experience after a transition from multipatient rooms to single-patient rooms.

Methods A cross-sectional survey of nurses was conducted before and after the move to a new hospital building in which all rooms in the pediatric critical care unit were single-patient rooms.

Results Nurses reported that compared with multipatient rooms, single-patient private rooms were more conducive to patients sleeping well at night and promoted a more normal sleep-wake cycle ($P < .001$). Monitors/alarms and staff conversations were the biggest factors that adversely influenced the environment for sleep promotion in both settings. Nurses were less annoyed by noise in single-patient rooms (33%) than in multipatient rooms (79%; $P < .001$) and reported improved exposure to sunlight.


NURSES’ PERCEPTIONS OF PEDIATRIC INTENSIVE CARE UNIT ENVIRONMENT AND WORK EXPERIENCE AFTER TRANSITION TO SINGLE-PATIENT ROOMS

By Sapna R. Kudchadkar, MD, M. Claire Beers, RN, MSN, Judith A. Ascenzi, RN, DNP, Ebaa Jastaniah, MD, and Naresh M. Punjabi, MD, PhD

Background The architectural design of the pediatric intensive care unit may play a major role in optimizing the environment to promote patients’ sleep while improving stress levels and the work experience of critical care nurses.

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IMPLEMENTING AN IN SITU MOCK CODE QUALITY IMPROVEMENT PROGRAM

By Megan D. Herbers, RN, BSN, and Joseph A. Heaser, RN, MAN, PCCN

Background The high risk and low volume of medical emergencies, combined with long periods between training sessions, on 2 progressive care units at Mayo Clinic, Rochester, Minnesota, established the importance of transforming how nursing staff are trained to respond to medical emergencies.

Objectives To increase confidence levels and improve nursing performance during medical emergencies via in situ simulation.

Methods An in situ, mock code quality improvement program was developed and implemented to increase nurses’ confidence while improving nursing performance when responding to medical emergencies. For 2 years, each unit conducted mock codes and collected data related to confidence levels and response times based on the recommendations in the 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.

Results In those 2 years, nursing staff response times for calling for help improved 12%, time elapsed before initiating compressions improved 52%, and time to initial defibrillation improved 37%. Additionally, staff showed an increase in perceived confidence levels. Staff reported their appreciation of the opportunity for hands-on practice with the equipment, reinforcing their knowledge and refining their medical emergency skills.

Conclusions In situ mock codes significantly improve response times and increase staff confidence levels. In situ mock codes are a quick and efficient way to provide hands-on practice and allow staff to work as a team.

Positive outcomes for patients after medical emergencies are dependent on the ability of first responders (nurses and patient care assistants) to deliver the care needed quickly and accurately during the critical first few minutes of a code situation. The skills and knowledge gained from basic life support/advanced cardiac life support (BLS/ACLS) training are quickly lost after these programs are completed. A lack of hands-on practice can lead to high anxiety and poor performance when nurses are faced with medical emergencies. The loss of knowledge and lack of proficient skills among nurses put patients at risk for adverse outcomes.

Patients who have a cardiac arrest in the hospital have a survival rate of approximately 10.0% to 23.9%. Nurses experience high levels of anxiety and have difficulty recalling the knowledge and demonstrating the skills required during medical emergencies. However, the use of mock code simulation can improve nurses’ confidence and performance. The high risk and low volume of medical emergencies, combined with the annual competency sessions and biannual recertification training, on 2 progressive care units at Mayo Clinic Hospital–Rochester, St Mary’s Campus, established the importance of transforming how nurses are trained to respond to medical emergencies.

Background

Through extensive research, the American Heart Association (AHA) discovered that the highest survival rates after cardiac arrest are in people who have a witnessed arrest, an initial rhythm of ventricular fibrillation or pulseless ventricular tachycardia, and chest compressions and defibrillation delivered quickly. Survival from a witnessed sudden cardiac arrest can be doubled or tripled if cardiopulmonary resuscitation (CPR) is administered quickly; for every 1 minute of delay in initiating CPR, the chances of survival decrease by 7% to 10%. Skills and knowledge retention decline following BLS/ACLS certification. In a mixed-method, explanatory study, Curran et al reported that the skills gained from these training methods progressively deteriorate in as little as 2 weeks, and substantial reduction in these skills occurs within 6 months of initial training. ACLS skills decrease at a faster rate than BLS skills; Dichtwald et al reported a retention success rate of 14% for ACLS versus 58% for BLS 12 months after training. Another downside of training in a formal BLS/ACLS class is that such training has little similarity to resuscitation in the hospital setting. Facilitators of BLS/ACLS programs often allow participants to verbalize their actions instead of performing them, taking away realism. The 2010 AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care recognize the need for additional training, stating that along with BLS/ACLS certification, organizations should provide periodic reinforcement or refresher information as needed for periodic assessment of staff members’ knowledge and skills. Although BLS and ACLS classes are necessary and beneficial, additional training methods are needed for nurses to maintain the skills, knowledge, and confidence needed during medical emergencies.

As first responders, nurses must have the skills and confidence to take action. As first responders to medical emergencies, nursing staff must have the confidence to take action and deliver the care needed during a code situation. Nursing staff are not as confident or comfortable as they would like to be when using their BLS/ACLS skills in a true code situation. In a quantitative study involving 250 staff nurses, Delac et al found that after participating in mock code training, nursing staff reported an increased level of confidence with initiating first-responder interventions, operating emergency medical equipment, and using hand-off communication. Lack of confidence can lead to hesitation and uncertainty about how to respond to medical emergencies, which can ultimately affect patient safety and contribute to adverse outcomes. Mock code training is a method proven to improve confidence levels among nursing staff.

At Mayo Clinic, nurses and nursing assistants are required to demonstrate proficiency in

About the Authors
Megan D. Herbers is a registered nurse and Joseph A. Heaser is an ambulatory nurse manager at Mayo Clinic, Rochester, Minnesota.

Corresponding author: Megan Herbers, RN, BSN, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (e-mail: herbers.megan@mayo.edu).
emergency medical response and proper use of equipment on an annual basis during competency evaluations. The competency program is designed to validate knowledge and skills but does not provide a learning opportunity for the nursing staff to have hands-on practice with the skills and knowledge needed during a code. Staff members are expected to demonstrate the skills during the competency check-off; if they are unable to complete the required steps, they are directed to review the resources available and to return at another time. Because of the limitations of the current training and competency system, the way in which staff members are trained to respond to medical emergencies needed to change. This is a reason why in situ simulation was chosen as the method of mock code delivery.

Many of the mock code programs found in published reports used in situ simulation training—holding the training session in a realistic training environment where care is actually delivered, such as patients’ rooms, waiting rooms, procedural areas, and showers, as well as during times when care is being provided to other patients.5,9,12 The benefits of in situ simulation training are that staff members are able to identify the location of emergency medical equipment, know how to call for help and activate the code team, learn to work as a team, and know what resources are available during an actual code. This type of training also offers the opportunity to identify issues with the existing code processes such as equipment availability, location, and functionality.14 In situ simulation training provides a realistic and interactive training environment that helps participants think critically about the location of emergency medical equipment and resources available to them, while holding onto the nonthreatening environment that can be created by simulation.9 Thus it appeared that the development and implementation of a unit-based in situ mock code program could improve performance and increase confidence levels among nursing staff.

Methods

In situ simulation was chosen as the method of delivery of the mock codes on 2 progressive care units to increase staff members’ confidence and knowledge, while improving performance when responding to medical emergencies. For 2 years, each unit conducted in situ mock codes quarterly and collected data related to confidence levels and response times according to the recommendations in the 2010 AHA guidelines. All staff members voluntarily completed a confidential electronic survey before the start of the mock code program to measure perceived confidence levels in responding to medical emergencies and handling the emergency medical equipment. The staff who participated in a mock code were sent the same survey within 2 weeks of completion of the mock code. The 3 survey questions were as follows:

1. I am confident in my ability to perform chest compressions on a patient who has no pulse.
2. Overall, I am confident in my ability to participate in a code 45 (medical emergency).
3. I am confident in my ability to be a team leader during a code 45.

Response options were categorized as strongly disagree, disagree, agree, and strongly agree. The changes in response proportions from the presurvey to the postsurvey were analyzed by using the χ² test. Dichotomous variables combining strongly disagree and disagree versus agree and strongly agree were also tested for change from the presurvey to the postsurvey by using the Fisher exact test. Statistical analysis was performed by using JMP 11.0 (SAS Institute Inc).

An observational evaluation tool was developed on the basis of the 2010 AHA guidelines for in-hospital arrest response and this institution’s annual competency program.8 The 2010 AHA guidelines recommend response times for assessing the patient and calling for help to be within 20 seconds of discovery, for initiating chest compressions to be within 60 seconds, and for delivering the first shock to be within 180 seconds.8 The evaluation tool measures these response times, proper CPR technique, and the ability of the nurses to use emergency medical equipment. Staff were not notified of these criteria before the mock codes.

Demographics

The in situ mock code program was introduced on a 36-bed medical and vascular surgical progressive care unit, which had 64 registered nurses and 19 nursing assistants, and a 33-bed thoracic surgical progressive care unit, which had 60 registered nurses and 9 nursing assistants. Nurses and nursing assistants who participated in the mock code program had a large span of experience, from 0 to 40 years. All nurses are BLS/ACLS certified; whereas the nursing assistants are BLS certified. Nurses and nursing assistants are required to complete annual assessments of competency in emergency medical response.
Results

Using the observational evaluation tool previously described, data were collected for 2 years to measure response times for calling for help, initiating compressions, and delivering the first shock. Figure 1 shows the median quarterly results for assessing and calling for help; a 12% improvement was seen from the first year to the second year. The improvement seen in assessing and calling for help directly affected the other 2 criteria, initiating chest compressions and delivering the first shock. Figure 2 shows the median results of time taken to initiate compressions (goal, within 60 seconds). Between the first year and the second year of implementing mock codes, this response time improved by 52%. Figure 3 shows the median results of initial defibrillation in running mock codes. The timing of initial defibrillation in the second year of running mock codes had improved by 37%. The results indicate a significant improvement in response times after initiation of the mock code program.

The results of the presurvey and the postsurvey are shown in Figure 4. The responses strongly disagree and disagree are considered unfavorable, and the responses agree and strongly agree are considered favorable. The question about confidence level related to initiating chest compressions had 90 responses for the presurvey: 82.0% of staff reported favorably and 18.0% of staff reported unfavorably. The 89 responses to the presurvey question about perceived confidence levels related to overall participation in a medical emergency were 86.5% favorable and 13.5% unfavorable. The question about confidence levels related to being a team leader during a medical emergency had 90 responses for the presurvey: 50.0% favorable and 50.0% unfavorable.

The postsurvey confidence results conducted within 2 weeks following a mock code received 86 responses, and revealed that staff members’ perceived confidence levels to initiate chest compressions increased to 100.0% favorable. The 86 responses to the postsurvey question about overall confidence levels for participating in a code 45 increased to 98.8% of staff responding favorably and 1.2% of staff responding unfavorably. The 86 responses to the postsurvey question about confidence levels to be a team leader during a code 45 increased to 67.4% favorable and 32.6% unfavorable.

The results indicate a significant improvement in response times after initiation of the mock code program. These response times were better than the times recommended in the 2010 AHA guidelines (Figures 1-3). A shift in results also is apparent from the presurvey to the postsurvey, with some staff reporting feeling more confident in their emergency response skills following an in situ mock code.

Discussion

The goal of the in situ mock code program was to improve staff response times in a medical emergency and increase nurse-perceived confidence levels in participating in a medical emergency. This quality
improvement project revealed that when assessing and calling for help, staff hesitated, which resulted in a delayed response. In addition, they did not trust their own assessment skills, were not treating the mock code as a real situation, and would frequently want to talk through it as often is done during the required annual competencies and biannual BLS/ACLS certification. It was observed that staff members who were initiating compressions were still using the old AHA guidelines of airway, breathing, circulation instead of the new 2010 AHA guidelines of circulation, breathing, airway, which delayed the initiation of compressions. This difference is important because the 2010 AHA guidelines recognize that the sooner critical elements in BLS (eg, chest compressions and early defibrillation) are initiated, the better the chances are for survival. In the first year of running mock codes, staff members would tend to finish their 2-minute cycle of compressions before initial defibrillation, were unsure with their assessment of the rhythm, and occasionally were unfamiliar with the equipment and hesitant to use it. Presurvey results indicated that staff were not as confident as they would like to be in their ability to participate in a medical emergency.

The mock code program provided mock codes via in situ simulation, which included a debriefing session, and provided staff an opportunity to respond to a medical emergency and have psychomotor practice with equipment in an environment with which they were familiar. After completing the mock code, the medical equipment was reviewed and a debriefing was done to identify things that went well and improvements that were necessary. All of the barriers that kept staff from responding in accordance to the 2010 AHA guidelines were discussed during the debriefing session after each mock code. In addition to defibrillation, staff members were given an opportunity to practice using the equipment for synchronized cardioversion and external pacing. Additional topics that were discussed during the debriefing session were alternative pad placement, ACLS medications, the 5-lead system, positioning of patients, bag mask ventilation, suction setup, back board placement, side rail position, compression depth, chest recoil, and additional resources available during a medical emergency. Given the variety of experience among all the staff members, every mock code stimulated new questions on different topics. The debriefing session following each mock code reduced barriers in the second year. Because of the frequent mock code scenarios, staff became more familiar with the environment of the in situ mock code, 2010 AHA guidelines, and best practices for a medical emergency.

Staff were supportive of the in situ mock code program and were grateful for the opportunity to refresh their knowledge and psychomotor skills. Each mock code took approximately 15 to 20 minutes to
complete, and staff appreciated that they did not have to prepare ahead of time, come to work on their day off, or wait in line for their turn. Staff comments regarding the mock code program were positive, referencing how much they enjoyed the teamwork, critical thinking, location, resources, and controlled environment. Staff reported feeling comfortable and safe to ask questions and make mistakes without experiencing repercussions. The in situ mock code program also empowered the nursing assistants to understand their role in participating in a code without ACLS training. Nursing assistants realized that they do not need to wait for the nurse to begin lifesaving BLS interventions in a medical emergency. The most common comment made by staff was their appreciation for the opportunity for hands-on practice with the equipment, reinforcing their knowledge and refining their medical emergency skills.

The mock code facilitators played an important role in the success and standardization of the in situ mock code program. They not only facilitated each mock code setup, implementation, and debriefing session, but they also facilitated enabling staff to come to the mock code by helping out on the unit with patient care when needed. Mock code facilitators also learned to adapt the mock code session to meet the needs of the staff and to take into consideration the pace of the unit. They conducted mock codes on a variety of shifts (evening, night, day, and weekend) to provide the opportunity to participate to as many staff members as possible. The use of the evaluation tool for each mock code scenario kept expectations clear with staff and ensured that mock codes were conducted in a similar fashion on both units. The standardization and collaboration of the in situ mock code program on both units contributed to its success.

Limitations identified were that participants’ performance and survey results were not matched, which makes it possible that staff could have submitted more than 1 survey if they participated in more than 1 mock code. The program used a variety of trained facilitators and different scenario setups, and the location of equipment varied on each unit, which may have influenced the results. Multiple mock code scenarios were run with the first scenario being a surprise, which could also make a difference in response times between the first mock code scenario and those that followed. Mock code participant dynamics and roles varied with each scenario.

Conclusion

Published evidence and knowledge gained from this quality improvement project support more frequent reviews of emergency response. In situ mock codes are a quick and efficient way to provide hands-on practice needed to promote muscle memory and allow staff members to work as a team. In addition, mock codes have significantly improved response times and increased staff members’ confidence levels. Standardizing the in situ mock code program not only contributed to its success and longevity, but made possible the participation of several other units within the institution. The debriefing session after each mock code scenario ensured that staff learned from the experience and found value in participating. The published evidence and positive results from the quality improvement project suggest that in situ mock codes are an effective means of educating nursing staff.

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None reported.

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1.0 Hour

Notice to CE enrollees:
This article has been designated for CE contact hour(s). The evaluation tests your knowledge of the following objectives:
1. Verbalize how mock codes help maintain skills, knowledge and confidence in adjunct with annual competency and biannual recertification.
2. Describe the quality improvement processes and tools used to explore the problem and develop interventions.
3. Identify success factors critical to the sustainability of this quality improvement intervention.

To complete evaluation for CE contact hour(s) for test #A1625052, visit www.ajcconline.org and click the “CE Articles” button. No CE test fee for AACN members. This test expires on September 1, 2019.

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Evidence-Based Review and Discussion Points

By Ronald L. Hickman, RN, PhD, ACNP-BC

Evidence-Based Review (EBR) is the journal club feature in the *American Journal of Critical Care*. In a journal club, attendees review and critique published research articles: an important first step toward integrating evidence-based practice into patient care. General and specific questions such as those outlined in the “Discussion Points” box aid journal club participants in probing the quality of the research study, the appropriateness of the study design and methods, the validity of the conclusions, and the implications of the article for clinical practice. When critically appraising this issue’s EBR article, found on pp 393-399, consider the questions and discussion points outlined in the “Discussion Points” box.

A lack of confidence in performing basic life support (BLS) and advanced cardiac life support (ACLS) is recognized as a clinical problem that can impede a nurse’s ability to effectively deliver these forms of life-sustaining care. A promising strategy, in situ mock codes, have been demonstrated to enhance confidence and retention of BLS and ACLS skills among nursing staff in acute care settings.

In situ mock codes are conducted in clinical settings that offer opportunities for nurses to practice delivering BLS and ACLS under psychologically nonthreatening conditions. Despite the promise of in situ mock codes, there remains insufficient evidence of the effects of this training on the nursing staff’s confidence levels and task performance.

To describe the effects of in situ codes on nursing staff training outcomes, the authors developed an in situ mock code program and evaluated its effects on nursing staff confidence levels and measures of task performance. This quality improvement project was conducted over a 2-year period and participants comprised 124 registered nurses and 28 nursing assistants from a medical-surgical or a thoracic progressive care unit at an academic medical center.

Participants attended in situ mock codes on the progressive care units. A brief survey was administered before and after the participants’ exposure to a simulated medical emergency. The survey contained 3 items to gauge the participants’ level of confidence in performing chest compressions, participating in a simulated medical emergency, and being the team leader. As a bachelor’s prepared nurse with minimal experience conducting a quality improvement project, Herbers stresses the importance of building a team. “I could never have done this project alone. From the very beginning it was a team effort between units, nurse education specialists, nurse managers, mock code facilitators and, of course, our participants,” she says. “We were all committed to increasing the confidence of our coworkers in a medical emergency,” adds Herbers.

Investigator Spotlight

This feature briefly describes the personal journey and background story of the EBR article’s investigators, discussing the circumstances that led them to undertake the line of inquiry represented in the research article featured in this issue.

Megan Herbers, RN, BSN, is a staff nurse at the Mayo Clinic in Rochester, Minnesota. For almost 10 years, she has provided nursing care to patients and their families on a thoracic progressive care unit. Herbers is actively engaged in clinical leadership and governance to promote nursing staff development and the quality of nursing care.

Motivated by personal experience, Herbers sought to make a difference. “The first code I was a part of as a nurse made me feel inadequate. Even though I had certified in BLS and ACLS just a few months earlier and had been off orientation for a few months, the skills I had learned did not stick with me in an emergency,” she says. “I never wanted to feel like that again. I wanted to feel confident and know that I did everything in my power to help the patient and my coworkers in an emergency. Fast forward a couple years and I was chair of the staff development committee and it became my mission to establish mock codes on my unit,” Herbers explains.

As a bachelor’s prepared nurse with minimal experience conducting a quality improvement project, Herbers stresses the importance of building a team. “I could never have done this project alone. From the very beginning it was a team effort between units, nurse education specialists, nurse managers, mock code facilitators and, of course, our participants,” she says. “We were all committed to increasing the confidence of our coworkers in a medical emergency,” adds Herbers.

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The findings of this study confirm the benefits of implementing an in situ mock code program to enhance confidence levels and skill performance among nursing staff. Participants demonstrated faster response times in calling for help, initiating chest compressions, and discharging the defibrillator. The authors also report improvements in the confidence levels in the nursing staff’s ability to perform chest compressions, effectively participate in a code, and serve as the team leader.

Information From the Authors

Megan Herbers, RN, BSN, lead author on this EBR article provides additional information about the study. She explains that this study began because of a recognized need for educational training after BLS and ACLS certification among the nursing staff on her progressive care unit.

The 2010 AHA guidelines for in-hospital cardiac arrest highlights the need to reinforce BLS and ACLS training more frequently than every 2 years, notes Herbers. She says it is well-known that the life-sustaining skills of BLS and ACLS deteriorate as early as 2 weeks after certification. “In situ mock codes reinforce and refresh the skills the nurse already knows,” Herbers says.

When asked if in situ mock codes make a difference, Herbers says, “It [exposure to an in situ mock code] has made our nurses more calm and able to give accurate reports during a medical emergency when compared with those in units that have not implemented in situ mock codes.” This feedback demonstrates that the in situ mock code program is making a difference, she adds. Given the clinical need and benefits of the program, Herbers has helped to implement the in situ mock program across 13 patient care divisions in the Mayo Clinic system.

Implications for Practice

Herbers encourages readers of the American Journal of Critical Care to consider implementing strategies that enhance nursing staff confidence levels and performance of BLS and ACLS skills. Herbers and coauthor Joseph Heaser believe in situ mock codes are an effective and efficient way to provide hands-on practice and experiential learning, which can improve nursing staff confidence levels and response times, and maximize patient outcomes. She hopes that this study’s results will be used to inform recommendations highlighted in clinical guidelines and support decisions to allocate institutional resources to implement in situ mock code programs across acute care settings.

eLetters

Now that you’ve read the article, create or contribute to an online discussion on this topic. Visit www.ajcconline.org and click “Submit a response” in either the full-text or PDF view of the article.

Discussion Points

A. Description of the Study
   - What is the purpose of the study?
   - What is an in situ mock code and what are the defining characteristics of this type of simulation?

B. Literature Evaluation
   - What factors influence nursing staff performance when faced with a medical emergency?
   - How rapidly do BLS and ACLS skills diminish after certification?

C. Sample
   - Who was eligible to participate in this study?
   - What were the exclusion criteria?

D. Methods and Design
   - Discuss the data collection procedures for this qualitative improvement project.
   - What were used as benchmarks for task performance?

E. Results
   - What were the major findings of this project?
   - How can you use the findings of this project to positively impact the quality of nursing care at your hospital?
Silver-Impregnated Dressings for Sternotomy Incisions to Prevent Surgical Site Infections in Children

By Sandra Staveski, RN, PhD, CPNP-AC, Claire Abrajano, RN, MS, WOCN, RNFA, CPNP, May Casazza, RN, MS, CPNP, Ellen Bair, RN, MS, CPNP, Hanson Quan, PA, Emily Dong, PA, Amy Petty, PA, Katie Felix, PA, and Stephen J. Roth, MD, MPH

Background
The consequences of surgical site infections can be severe and range from short-term delays in discharge from the hospital to life-threatening infections such as mediastinitis.

Objectives
To evaluate the effectiveness of silver-impregnated dressings in decreasing surgical site infections in children after cardiac surgery.

Methods
A randomized, controlled trial was used to compare silver-impregnated dressings (59 participants) with standard dressings (58 participants). The study team supervised all dressing changes after a sternotomy and ensured adherence with the hospital’s bundle for reduction of surgical site infections. The ASEPSIS tool was used to evaluate sternal wounds for evidence of infection.

Results
The 2 groups had comparable Risk Adjustment for Congenital Heart Surgery scores, age, sex, weight, height, operating room characteristics, and number of chest tubes and/or pacemaker wires. No surgical site infections occurred in any study participant. Infections did occur, however, during the same period, in cardiac surgical patients who were not enrolled in the study.

Conclusions
The evidence did not support the superiority of silver-impregnated dressings for prevention of surgical site infections in children after cardiac surgery. Adherence to a bundle for prevention of surgical site infections may have decreased the incidence of such infections in the study population during the study period. (American Journal of Critical Care. 2016;25:402-408)
In clinical investigations,\textsuperscript{1,2} surgical site infection (SSI) after operative procedures for congenital heart defects in infants and children has been cited as a major source of morbidity, mortality, and financial cost. The guideline\textsuperscript{3} from the Centers for Disease Control and Prevention for the prevention of SSI defines the entity (for all age groups and surgery types) as an infection that occurs within 30 days of the operation or within 1 year of implantation of a foreign material and/or diagnosis of an organ or space infection by a surgeon or attending physician. SSIs after cardiovascular surgery comprise a spectrum of disease ranging from superficial infections to deep sternal wound infections (also known as mediastinitis), and they often result in increased hospital stays.\textsuperscript{1} The incidence of SSIs was reported by 38 pediatric cardiac centers in North America as a mean rate of 1.53\% (range, 0\%-9.09\%).\textsuperscript{2} In North American children’s hospitals, the mean added hospital cost attributed to a cardiovascular surgical SSI in children was $28,000 per child.\textsuperscript{2}

Prevention of SSIs has become a quality improvement priority for institutions across the United States.\textsuperscript{4} Practice bundles have been heralded as an effective and systematic way to deliver preventive measures focused on a specific condition.\textsuperscript{2,5,6} Haraden\textsuperscript{6} defines a bundle as a set of 3 to 5 practices that must all be completed to achieve successful delivery of health care. The practices outlined in the bundle are all required, and if any 1 of the items is removed, the bundle of measures may no longer be effective. Despite comprehensive efforts associated with bundling, SSIs continue to occur and cause patients harm. Therefore, other interventions for SSI reduction deserve further exploration. For example, silver, which has a long history of antimicrobial activity, is well documented in the management of burns and other wound infections in both children and adults.\textsuperscript{7} The use of silver-impregnated dressings has been described in the care of adults after laminectomy, after wound grafts associated with plastic surgery, and after coronary artery bypass grafting.\textsuperscript{8-10} However, in a systematic review on the efficacy of silver-impregnated dressings, Hermans\textsuperscript{11} described variable clinical results. Currently, whether or not silver-impregnated dressings reduce the incidence of SSIs in children after cardiac surgery is unknown. The purpose of this study was to examine the efficacy of silver-impregnated dressings on sternotomy wounds for the prevention of SSIs in children after cardiac surgery.

**Methods**

**Design**

A prospective randomized controlled clinical trial was used to compare the effectiveness of silver-impregnated dressings with that of standard dressings on SSI reduction in children after cardiac surgery at Lucile Packard Children’s Hospital Stanford, Palo Alto, California. The study was approved by the appropriate institutional review board.

**Participants**

The participants were newborns to adolescents (<18 years old) with congenital heart disease who had a median sternotomy incision as a component of congenital heart surgery. Potential participants were excluded from enrollment if they were known to be allergic to silver or other metals, expected to have a thoracotomy instead of a sternotomy, anticipated to have delayed sternal closure, or they or their parents declined participation in the study. The study period was May 19, 2008, to July 22, 2011. The control group consisted of participants who received a standard gauze dressing adhered with paper tape to maintain integrity immediately after the surgical wound was closed in the operating room. The silver or experimental group consisted of participants who had a strip of silver-impregnated dressing material applied over the sternotomy incision (in accordance...
Participants were monitored throughout their hospitalization, and a 30-day follow-up call was made.

Bundle measures included preoperative, age-appropriate skin cleansing with either soap and water or 2% chlorhexidine gluconate cloths.

with all of the manufacturer’s requirements) and covered with gauze and adhered to the skin with paper tape. The sample size was chosen for a clinically important effect size of 0.5 in the detection of differences in SSI rates with a greater than 70% power at \( \alpha = .05 \). Participants were withdrawn from the study if the surgeon placed an alternative dressing (eg, 2-octylcyanoacrylate tissue adhesive) on the patient, medical reasons required withdrawal (eg, unanticipated delayed sternal closure), the health care team’s specific actions did not abide by the study protocol or SSI bundle, the patient’s family withdrew the child from the study, or the participant had the surgery at another facility in the hospital’s cardiac surgery network. Patients who received cyanoacrylate tissue adhesive dressings on their surgical wounds were excluded because the adhesive would provide an additional barrier protection that could further prevent SSIs, use of the adhesive was not standard of care when the study began, and the adhesive was the surgeon’s preference for a limited number of cases such that this potential study group or arm would not achieve statistical significance.

Materials

Acticoat and Acticoat Flex 3 antimicrobial barrier dressings (Smith and Nephew Corp) were used as the experimental dressing in the trial. The silver material was a conformable, nanocrystalline silver-coated, antimicrobial barrier dressing that allows the passage of exudate and can be affixed for up to 3 days.\(^{12,13}\) Although Acticoat and Acticoat Flex 3 have different substrates, both contain nanocrystalline silver and provide an equivalent antimicrobial barrier with proven efficacy against highly antibiotic-resistant organisms, a broad spectrum of gram-positive and gram-negative bacteria, and fungal wound pathogens.\(^{14}\) The chief difference between Acticoat and Acticoat Flex 3 is that the latter is more flexible and therefore more comfortable for patients.\(^{14}\) Our institution changed to Acticoat Flex 3 during our study. Because both products provided similar antimicrobial barriers, we chose to simplify the nursing care by using the hospital’s new product. The control dressing consisted of sterile gauze. Paper tape was used to affix both experimental and control dressings.

Measures

A variety of measures were used in the study, including descriptive statistics, a risk-adjustment index, a tool to monitor adherence with the SSI bundle, overall cardiovascular SSI rates during the study period, and wound assessment via a validated instrument, the ASEPSIS tool.\(^ {15-17}\) The SSI bundle measures included preoperative, age-appropriate skin cleansing with either soap and water or 2% chlorhexidine gluconate cloths, as dictated by hospital policy; use of an appropriate antiseptic agent for skin preparation in the operating room for age, according to hospital policy (eg, betadine, chlorhexidine); and appropriate administration (ie, both the agent and timing of the dose or doses) of a standard prophylactic intravenous antimicrobial agent.

Study Data

Age at the time of surgery, sex, operating room details, invasive tubes or wires associated with surgery (eg, chest tubes, pacemaker wires), serum metabolic profile, and the score on the Risk Adjusted Classification for Congenital Heart Surgery (RACHS-1) were recorded for each participant. The RACHS-1 score is used to categorize in-hospital mortality and length of stay for children undergoing surgery for congenital heart disease according to cardiac diagnosis.\(^ {15}\) The ASEPSIS tool is a quantitative scoring tool used to measure severity of wound infections; a numerical score is acquired by using objective criteria based on the wound appearance and infection management.\(^ {17}\) Higher scores are allocated for antibiotic treatment (10 points), drainage of pus under local anesthesia (5 points), debridement of the wound under general anesthesia (10 points), and an inpatient stay related to wound infection of more than 14 days (5 points). The ASEPSIS score is described as follows: 0 to 10 points, satisfactory healing; 11 to 20 points, disturbance of healing but no infection; 21 to 30 points, minor wound infection; 31 to 40 points, moderate wound infection; and 40 to 70 points, severe infection.\(^ {17}\) Adherence with the bundle elements (described in the Measures section) was recorded as yes or no. SSIs were recorded as the number of superficial and deep incisional infections that met the criteria of the Centers for Disease Control and Prevention.

Procedures

Interdisciplinary team support was solicited for the investigation. Once agreement for adherence with the SSI bundle was established, all health care staff members were educated on the study protocol. Potential study participants were approached preoperatively and informed about the investigation; consent was obtained by the preoperative advanced practice team. Patients were
counseled that nonparticipation would not adversely affect care delivery and that they could withdraw from the study at any time. Participants were assigned to either the control group or the experimental group randomly (a member of the advanced practice team chose an envelope with group assignment). Signage identifying that the patient was enrolled in the investigation was placed on the participant’s medical record to alert operating room staff of study participation and placement of the appropriate surgical dressing. On the basis of the patient’s group assignment, the surgical team (eg, surgeon, operating room nurse, or both) applied the appropriate dressing immediately after closure of the sternal incision in the operating room, and the dressing remained in place for 48 hours. The experimental group had Acticoat or Acticoat 3 dressings cut to an appropriate size, moistened with sterile water as recommended by the manufacturer, applied directly to the incision, and covered with a secondary gauze dressing. Participants in the control group had a gauze dressing applied and secured with paper tape.

At a standardized time, for both study groups, the operative dressing was removed by a bedside nurse and thereafter changed daily until postoperative day 5 under the supervision of the study team. On day 5, dressings were removed, and the incision was left exposed to air (with the exception of participants who were still tracheally intubated). Wound assessments were performed by the study team by using the ASEPSIS tool, and all dressing changes were monitored to ensure meticulous wound care and assessment. Participants were monitored throughout their hospitalization, and a 30-day follow-up call was used to obtain data on SSIs in patients who had been discharged. An ASEPSIS score was calculated, and any scores between 21 and 70 were considered indicative of infection.17

Statistical Analysis

Descriptive statistics were used to describe the participants. Means and standard deviations were generated via a $t$ test. All data were analyzed by using PASW Statistics 18 (SPSS). SSI rates were calculated by including the number of SSIs in the numerator and the number of open and closed cardiac operative procedures in the denominator during a 30-day period from surgery, as reported by the institution’s infection prevention department.

Results

A total of 117 participants were randomized to the 2 groups and completed the study per protocol (59 participants in the silver group and 58 in the standard group). No SSIs occurred in either experimental or control participants who completed the study per the protocol. Of note, 3 participants experienced SSIs; however, their care deviated from the SSI bundle (and study protocol), and they thus were excluded from the analysis. Further review of these 3 patients’ cardiac histories, underlying physiological status, and perioperative courses revealed the following: a 4-month-old infant with hypoplastic left heart syndrome and DiGeorge syndrome (with known associated immunocompromise) who underwent a bidirectional Glenn palliation, a 4-year-old child with an interrupted aortic arch and a previous history of mediastinitis who underwent a right ventricle-to-pulmonary artery conduit change, and a 17-year-old obese child with aortic stenosis who underwent an aortic valve repair without appropriate antibiotic prophylaxis. Although deviations in study protocol occurred, these 3 children represented a more complex subset of patients who most likely were at increased risk for SSI.

An additional 33 patients withdrew or were withdrawn from the study for a variety of reasons that included cancellation of the operation, family decision to withdraw, and noncompliance with SSI protocol. The 2 study groups had comparable RACHS-1 scores, ASEPSIS scores, weight, height, age group, and number of chest tubes and pacemaker wires, and metabolic profiles. The study groups had different means for operative time, cardiopulmonary bypass time, and cross-clamp time (see Tables 1, 2, and 3). During the study period, the overall cardiovascular surgery SSI rate in children ranged from 1.4 per 100 cases to 4.9 per 100 cases (Table 4). Possible causes for the change in SSI rates could be variable compliance with the SSI bundle and alterations in patients’ complexity.

Discussion

Silver or sulfadiazine has been extensively used in the management of burn wounds.12,13,18,19 Silver-containing dressings have been marketed as bactericidal against a large number of gram-positive and gram-negative organisms for infants and children.13 The results in the reduction of wound infections are mixed.19 Huckfeldt et al10 found that use of silver nylon dressings was statistically related to lower mediastinitis rates in adults. However, the number of participants in the sample was small,30 and the results were therefore not generalizable. Our results revealed no evidence to support the use of silver-impregnated dressings in children after cardiac surgery as a method to prevent SSI.
We found that concentrated focus, support, and observation by an interdisciplinary team who followed a protocol to prevent SSI may lead to elimination of such infections without adding costs associated with use of a silver-impregnated dressing. This result could be due to the Hawthorne effect, a form of reactivity in which participants in a study improve or modify their behavior when experimentally measured simply because they are being studied, and not in response to one of the experiment’s interventions.

Alternatively, our results suggest that adherence to an SSI bundle is associated with a reduction in the number of SSIs. The Institute for Healthcare Improvement6 promotes the use of an SSI bundle to prevent a majority of SSIs in all patients. The SSI bundle we used in our study was in compliance with the standards of the Institute for Healthcare Improvement. Our findings support adherence with established SSI prevention bundles because use of the bundles may help reduce SSIs.

Finally, our study participants had low RACHS-1 scores, but the ability of RACHS-1 scores to be predictive of SSI risk rather than mortality in children undergoing cardiothoracic surgery continues to be unclear.20 The performance of multiple perioperative medical interventions enhances the risk for SSI in young children who require cardiac surgery and reinforces the importance of compliance with SSI bundles.20 Effective compliance with SSI bundles requires an identified champion, frequent staff education (and reeducation), use of checklists, preoperative and postoperative education of children’s parents or guardians, tracking use of the appropriate bundle, and frequent communication with the entire interdisciplinary team. Our findings support meticulous attention to SSI bundles and an identified champion who tracks performance of each member of the health care team in the effort to reduce SSIs.

Limitations

Although our study was a randomized, controlled trial with use of current best practices, it has limitations. It was done at a single center, and therefore the results may not be generalizable. We acknowledge that our study was affected by the unavoidable Hawthorne effect. We based our calculation of the number of participants in the study on historic SSI rates at our center. Because no SSIs occurred in either treatment group among participants who successfully completed the study protocol, we were unable to make a meaningful comparison. Additionally, data on a high number of patients were excluded from the analysis because of protocol deviations or withdrawal.

Conclusion

Although adult cardiac surgery patients who receive silver-containing dressings have fewer mediastinal infections than do patients who receive a dry
gauze dressing (P<.05). The children in our study who had cardiac surgery did not. Patients’ age and associated healing capabilities may be a factor in the need for wound prophylaxis. We found no evidence to support the use of silver-impregnated dressings for SSI prevention in children after cardiac surgery in a randomized, controlled trial comparing silver dressings with standard dressings. None of the study participants had an SSI. However, SSIs occurred in other children after cardiovascular surgery who were not enrolled during the study period. Our findings suggest a potential link between adherence to a SSI bundle and a decreased incidence of SSI.

ACKNOWLEDGMENTS
This study was performed while Sandra Staveski was a nurse practitioner in the cardiovascular ICU at Lucile Packard Children’s Hospital Stanford. We thank our bedside nurse dressing evaluation team from the Children’s Heart Center for all their support and efforts. The work of nurse practitioner in the cardiovascular ICU at Lucile Packard Children’s Hospital Stanford. We thank our bedside nurse dressing evaluation team from the Children’s Heart Center for all their support and efforts. The work performed in this study was done in accordance with the appropriate institutional review body and carried out according to the ethical standards set forth in the Helsinki Declaration of 1975.

FINANCIAL DISCLOSURES
We acknowledge the generous support of the Legacy Foundation, Stanford, California, for funding our study.

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Background Baseline health status influences outcomes of severe sepsis.

Objective To determine if recent infection is a marker of poor health in patients with hematologic malignant tumors and severe sepsis by modifying the Sequential Organ Failure Assessment (SOFA) score to account for infection.

Methods Medical records of the first 50 patients with hematologic malignant tumors and severe sepsis admitted from September 1, 2009 to September 1, 2014, were reviewed to derive a modified SOFA score. The predictive accuracy of the modified score was compared with that of the unmodified score and the Acute Physiology and Chronic Health Evaluation (APACHE) II score for the 196 subsequent patients.

Results The area under the receiver operator characteristic curve was 0.73 (95% CI, 0.66-0.80) for the modified score, 0.68 (95% CI, 0.61-0.76) for the unmodified score, and 0.65 (95% CI, 0.58-0.73) for the APACHE II score. The modified score was better for discriminating survivors from nonsurvivors than the unmodified score (P=.005) and the APACHE II score (P=.04). After adjustments for the modified score and age, only increased days from hospital to intensive care unit admission was significantly associated with 30-day mortality.

Conclusion Modifying the SOFA score to account for infections before admission to the intensive care unit improved the prognostic usefulness of the scores for patients with hematologic malignant tumors and severe sepsis. (American Journal of Critical Care. 2016;25:409-417)
Severe sepsis, characterized by systemic inflammation and acute organ dysfunction due to infection, is estimated to affect 1 million to 3 million patients in the United States each year and to be responsible for 250,000 to 350,000 in-hospital deaths. Predicting the outcome for any individual patient with severe sepsis is difficult because the outcome depends on both the patient’s health before infection and the degree of organ dysfunction after infection. Moreover, although a patient’s health is related to his or her comorbid conditions, clearly not all patients with a common comorbid condition are in the same state of health before sepsis occurs.

We found previously that among patients with hematologic malignant tumors, an inpatient infection in the 90 days before a bloodstream infection was common and was associated with greater 30-day mortality after the bloodstream infection. We hypothesized that patients who recently survived an infection before the occurrence of severe sepsis were in a poorer state of health than were patients with no history of infection before sepsis. Thus, we sought to improve the predictive accuracy of the Sequential Organ Failure Assessment (SOFA) score for patients with hematologic malignant tumors and severe sepsis by modifying the assessment to include points for having survived a recent infection.

Methods

Study Location and Patients

This study was conducted at the University of Chicago Medical Center, Chicago, Illinois, a 568-bed, university-affiliated, urban teaching hospital. Administrative billing records were used to identify all patients with hematologic malignant tumors (International Classification of Diseases, Ninth Revision codes 200-208) who were admitted to the adult medical intensive care unit (ICU) from September 1, 2009, to September 1, 2014. Medical records were manually reviewed, and a patient’s data were included if the patient had a diagnosis of severe sepsis or septic shock at the time of ICU admission according to the 1992 consensus definition. Patients were excluded if their malignant tumor was in complete remission and they were no longer under the care of an oncologist. Only the first ICU admission for severe sepsis for each patient was included as an index case. The University of Chicago institutional review board approved this study and waived the need to obtain informed consent. The study was performed in accordance with the ethical standards set forth in the 1964 Declaration of Helsinki and its amendments.

Study Design and Data Collection.

We used a retrospective cohort design. Baseline demographic, malignant tumor, and ICU variables were collected by reviewing each patient’s electronic medical record, which included nursing documentation, laboratory values, microbiology data, physicians’ notes, radiology reports, and hospital discharge summaries. A patient was determined to have poor performance status if he or she could not perform activities of daily living at the time of hospital admission. The SOFA score includes 0 to 4 points for increasing severity of acute organ failure for each of 6 organ systems. In this study, we calculated a SOFA score only on the first day of ICU admission. The primary outcome was death during the first 30 days after ICU admission.

For each patient, the most recent inpatient infection that occurred within 90 days before ICU admission was recorded. Infections were categorized as bacterial on the basis of the Centers for Disease Control and Prevention definition. Infections were categorized as fungal if they met definite or probable criteria according to an international consensus definition. Infections were categorized as viral if clinical findings suggested a viral cause and results of culture, polymerase chain reaction assay, or histopathological findings indicated a virus. Inpatient infections treated at outside institutions were also included if documented in the medical records.
Score Derivation

The 50 patients admitted from September 1, 2009, to September 1, 2010, were evaluated to derive the modified SOFA (SOFA-HM) score. The variable “days since most recent infection” was initially treated as a continuous variable; this variable was assigned a value of 91 for patients who did not have an inpatient infection in the 90 days before ICU admission. To determine the nature of the relationship between days since most recent infection and 30-day mortality independent of the SOFA score, we adjusted the value of days since most recent infection by dividing it by the expected mortality on the basis of the SOFA score for each patient. We determined that a linear model approximated the relationship between risk for death and days since most recent infection because the addition of days since most recent infection squared term did not significantly alter the model (Figure 1).

Because an inherent error exists in determining the exact day that an infection started, we created 3 point categories rather than 5. A total of 0 points was assigned for no infection within 90 days, 2 points for an infection 31 to 90 days before ICU admission, and 4 points for an infection 30 days or fewer before ICU admission. In univariate analysis, the odds ratios for death for each 2-point increase on the infection score were within the 95% CIs of the odds ratios for death for most of the other components of the SOFA score (Table 1). Thus, the infection score was given the same weight as the other components of the SOFA score (Table 2). Table 3 gives the distributions of earlier infection points for patients in the derivation and validation cohorts.

Score Validation

For the subsequent 196 patients in the cohort admitted from September 1, 2010, to September 1, 2014, the predictive performance (calibration and discrimination) of the SOFA-HM score was compared with that of the SOFA score and the APACHE II score.4,7 Calibration is the degree to which actual outcomes match their predicted incidence. Calibration was assessed by using the Hosmer-Lemeshow goodness-of-fit test C statistic for observed and expected numbers of survivors and deaths across all of the strata of probabilities of death. A high P value (P > .05) indicates a good fit for the model. Calibration curves were also created by plotting predicted mortality rates stratified by 20% intervals of mortality risk (x-axis) against observed mortality rates (y-axis). Discrimination is the degree to which a score can be used to identify patients at highest risk for death. The discrimination was determined by calculating the area under the receiver operating characteristic curve and the 95% CI.

Figure 1 Mortality vs days since most recent infection (adjusted for expected mortality) among the 50 patients in the derivation cohort.

Table 1

Univariable models of relationships between each component of the SOFA-HM score and 30-day mortality for 50 patients in the derivation cohort (17 survivors, 33 deaths)a

<table>
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<th>Score</th>
<th>Points</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>P</th>
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<td>1-2</td>
<td>0.98</td>
<td>0.21-4.58</td>
<td>.98</td>
</tr>
<tr>
<td></td>
<td>3-4</td>
<td>1.33</td>
<td>0.28-6.33</td>
<td>.72</td>
</tr>
<tr>
<td>Coagulation</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>1-2</td>
<td>1.5</td>
<td>0.27-8.45</td>
<td>.65</td>
</tr>
<tr>
<td></td>
<td>3-4</td>
<td>1.33</td>
<td>0.30-5.96</td>
<td>.71</td>
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<tr>
<td>Liver</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>1-2</td>
<td>0.64</td>
<td>0.17-2.48</td>
<td>.52</td>
</tr>
<tr>
<td></td>
<td>3-4</td>
<td>0.92</td>
<td>0.07-11.2</td>
<td>.95</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>1-2</td>
<td>1.75</td>
<td>0.39-7.95</td>
<td>.47</td>
</tr>
<tr>
<td></td>
<td>3-4</td>
<td>0.98</td>
<td>0.23-4.25</td>
<td>.98</td>
</tr>
<tr>
<td>Central nervous system</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>1-2</td>
<td>1.2</td>
<td>0.35-4.16</td>
<td>.77</td>
</tr>
<tr>
<td></td>
<td>3-4</td>
<td>NA b</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Renal</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>1-2</td>
<td>1.85</td>
<td>0.51-6.69</td>
<td>.35</td>
</tr>
<tr>
<td></td>
<td>3-4</td>
<td>1.94</td>
<td>0.29-13.2</td>
<td>.50</td>
</tr>
</tbody>
</table>

Abbreviations: SOFA-HM, Sequential Organ Failure Assessment–hematologic malignant tumor; NA, not applicable; —, reference.

a For the components of the SOFA score, the patients with 1-2 points were grouped and patients with 3-4 points were grouped.

b All patients died.
**Data Analysis**

Continuous variables were reported as medians and interquartile ranges. The t test, Mann-Whitney test, χ² test, or Fisher exact test was used in bivariate testing, as appropriate, to determine if differences between groups were significant. Logistic regression analysis was used to identify risk factors present at the time of ICU admission that were independently associated with 30-day mortality after adjustments for age and SOFA-HM score. Initial models included all recorded variables; backward selection was then used to determine a final model. All tests were 2-sided, and a P of .05 or less was considered significant. All analyses were performed by using STATA 13.1 software (StataCorp).

**Results**

Between September 1, 2009, and September 1, 2014, a total of 433 distinct patients with hematologic malignant tumors were admitted to the medical ICU. A total of 27 patients (6.2%) were excluded from the study because their tumors were in complete remission and the patients were no longer being treated by an oncologist. A total of 246 patients (57%) met the criteria for severe sepsis. Among the patients with severe sepsis, 98 (40%) had an inpatient infection in the 90 days before ICU admission for severe sepsis. Of these earlier infections, 11 (11%) occurred at outside hospitals. The most common organ systems involved were respiratory and primary bloodstream for both index cases and previous infections (Table 4). When the derivation and validation cohorts were examined as a group, each 2-point increase in infection score was an independent risk factor for death. The magnitude of the effects was similar to the magnitudes of the respiratory, coagulation, and central nervous system components of the SOFA score (Table 5). The liver, cardiovascular, and renal scores were not independently associated with 30-day mortality.

Figure 2 shows the calibration curves for the SOFA-HM, SOFA, and APACHE II scores. Hosmer-Lemeshow C statistic P values for the SOFA-HM, SOFA, and APACHE II scores were .42, .25, and .31, respectively, indicating that all scores fit the data well. Distribution of numbers of patients across all strata of expected mortality were more even for the SOFA-HM score than for the SOFA and APACHE II scores. The SOFA-HM score enabled discrimination of survivors from nonsurvivors significantly better than the SOFA score and the APACHE II score did (Figure 3). The area under the receiver operating characteristic curve was 0.73 (95% CI, 0.66-0.80) for the SOFA-HM score, 0.68 (95% CI, 0.61-0.76) for the SOFA score (P = .005 for difference with SOFA-HM), and 0.65
(95% CI, 0.58-0.73) for the APACHE II score ($P = .04$ for difference with SOFA-HM).

In the validation cohort, 105 patients (54%) died during the first 30 days after ICU admission (Table 6). According to bivariate analysis, a relapsed /progressive hematologic malignant tumor ($P = .008$) and a greater number of days in the hospital before ICU admission ($P = .02$) were positively and significantly associated with mortality. Patients who died were more likely than were survivors to require invasive mechanical ventilation and vasoactive agents ($P < .001$). After adjustments for SOFA-HM score and age, the only variable significantly associated with 30-day mortality was increased days from hospital to ICU admission (Table 7).

**Discussion**

In this study, we used a novel approach to improve the predictive accuracy of an ICU scoring system for patients with hematologic malignant tumors. In previous investigations, scoring systems have been modified by altering the weights of components or by combining aspects of different scoring systems. However, we hypothesized that a main limitation of these scoring systems is that they are missing variables for patients at high risk for death due to sepsis.
As a whole, patients with hematologic malignant tumors are among patients with the highest risk for severe infections and for death due to the infections.10 Our mortality rate of 54% is similar to the previously reported rate.11-14 However, all patients with hematologic malignant tumors do not have the same baseline risk for death due to severe sepsis. In our study, ICU mortality was inversely associated with time since most recent infection, independent of the degree of acute organ failure. As a result, we were able to derive a point system for the previous infection variable and incorporate the system into the SOFA score.

The SOFA-HM score was superior to the SOFA and APACHE II scores in 2 ways. First, the SOFA-HM score was significantly better than the SOFA and APACHE II scores for discriminating survivors from nonsurvivors. Second, the SOFA-HM scores had the most even distribution across all strata of expected mortality. ICU scoring systems may be used more often clinically if greater percentages of patients have either very high or very low expected mortality. The main limitation of the SOFA-HM score is that automating its determination could be challenging. Currently, a clinician must have access to and must

### Figure 2
Calibration curves for the Sequential Organ Failure Assessment–hematologic malignant tumor (SOFA-HM), SOFA, and Acute Physiology and Chronic Health Evaluation (APACHE) II scores for the 196 patients in the validation cohort. Solid line indicates mean observed mortality; dashed line indicates expected mortality.

<table>
<thead>
<tr>
<th>A. SOFA-HM score</th>
<th>B. SOFA score</th>
<th>C. APACHE II score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observed mortality, %</td>
<td>Stratum of expected mortality, %</td>
<td>Percentage of cohort</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>25</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>50</td>
<td>40</td>
<td>20</td>
</tr>
<tr>
<td>75</td>
<td>60</td>
<td>30</td>
</tr>
<tr>
<td>100</td>
<td>80</td>
<td>40</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D. Stratum of expected mortality, %</th>
<th>Stratum of expected mortality, %</th>
<th>Percentage of cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>25</td>
<td>25</td>
<td>10</td>
</tr>
<tr>
<td>50</td>
<td>50</td>
<td>20</td>
</tr>
<tr>
<td>75</td>
<td>75</td>
<td>30</td>
</tr>
<tr>
<td>100</td>
<td>100</td>
<td>40</td>
</tr>
</tbody>
</table>
After adjustments for age and SOFA-HM score, the only variable that remained significantly associated with mortality was time from hospital admission to ICU admission. Results of other studies of critically patients with hematologic malignant tumors also indicate that a greater number of days in the hospital before critical illness is associated with increased mortality. We also confirm the findings of previous investigators that variables associated with malignant tumors (type of tumor, recent chemotherapy, neutrophil count) are not associated with mortality due to critical illnesses. The explanation for this surprising finding could be the fact that patients must be in a relatively good state of health to be eligible for chemotherapy. In addition, patients with neutropenia may have a more transient risk for severe infection than do patients who are immunosuppressed because of other reasons.

Because patients with severe sepsis have high prevalence of chronic diseases, they often require medical care in the months leading up to a hospitalization for severe sepsis. Prescott et al estimated that in the year before an episode of severe sepsis, patients had mean of 1.44 hospitalizations and 24.2 days in the hospital per patient-year. Although the need for frequent health care most likely signifies a state of poor health, previous use of health care alone does not affect outcomes of sepsis independent of physiologically based scores. Our findings suggest that in order to discover significant associations between previous use of health care and outcomes of sepsis, patients should be grouped according to comorbid conditions and the focus should be on infectious instead of noninfectious reasons for hospitalization.

Multiple reasons could explain why patients who survived recent infections could be at greater risk of death from future episodes of severe sepsis. A previous infection could be associated with other aspects of care that portend a poor prognosis. For instance, a history of recurrent infections may delay chemotherapy or alter goals of care for patients with aggressive malignant tumors. Also, patients with previous infections may be at higher risk for subsequent infections caused by virulent, antibiotic-resistant organisms than are patients with no history of infection. Finally, patients who survive an infection may enter an immune recovery phase; patients who experience severe sepsis during this recovery phase may have the highest risk for death.

Clearly, the main limitation of our study was the small number of patients in the sample. Although we derived the SOFA-HM score among a subgroup of 50 patients, we showed that the infection score influenced mortality to a similar extent as the other components of the SOFA score in the whole 246-patient cohort. Another limitation was that this study was conducted at a single health care center, a characteristic that potentially affects the generalizability of the findings. Clinicians in our ICU care for large numbers of critically ill patients with hematologic malignant tumors, and many of the patients have relapsed or progressive diseases. Thus, we suspect that the SOFA-HM might not be more accurate than the SOFA score in health care systems where most patients have newly diagnosed cancer and have less previous health care exposure.

Overall, our findings support the hypothesis that a patient’s baseline health influences outcomes from severe sepsis independent of severity of acute illness. A major weakness of ICU scoring systems is that even though points are assigned for comorbid conditions, the scores do not adequately account for a patient’s chronic health status. Among patients who are at high risk for severe sepsis, history of recent infection should be investigated as a surrogate for poor health. We suggest that clinicians who work at centers that care for many patients with hematologic malignant tumors investigate the predictive ability of the SOFA-HM score at their institutions. If the SOFA-HM is a better predictor of outcomes compared with other scoring systems, as it was in our study, it should be used to benchmark mortality rates over time and stratify patients who are enrolled in clinical trials.
### Table 6
**Bivariate associations between patients’ characteristics and mortality for the 196 patients in the validation cohort**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Died during first 30 days (n = 105)</th>
<th>Alive (n=91)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, median (IQR), y</td>
<td>62 (50-70)</td>
<td>59 (50-67)</td>
<td>.12</td>
</tr>
<tr>
<td>Male sex, No. (%)</td>
<td>61 (58)</td>
<td>54 (59)</td>
<td>.86</td>
</tr>
<tr>
<td>Race, No. (%)</td>
<td></td>
<td></td>
<td>.34</td>
</tr>
<tr>
<td>White</td>
<td>62 (59)</td>
<td>57 (63)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>31 (30)</td>
<td>29 (32)</td>
<td></td>
</tr>
<tr>
<td>Other race</td>
<td>12 (11)</td>
<td>5 (5)</td>
<td></td>
</tr>
<tr>
<td><strong>Hematologic malignant tumor</strong></td>
<td></td>
<td></td>
<td>.76</td>
</tr>
<tr>
<td>Acute myeloid leukemia, No. (%)</td>
<td>48 (46)</td>
<td>34 (37)</td>
<td></td>
</tr>
<tr>
<td>Acute lymphocytic leukemia, No. (%)</td>
<td>13 (12)</td>
<td>9 (10)</td>
<td></td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma, No. (%)</td>
<td>19 (18)</td>
<td>22 (24)</td>
<td></td>
</tr>
<tr>
<td>Hodgkin lymphoma, No. (%)</td>
<td>2 (2)</td>
<td>5 (5)</td>
<td></td>
</tr>
<tr>
<td>Multiple myeloma, No. (%)</td>
<td>11 (10)</td>
<td>9 (10)</td>
<td></td>
</tr>
<tr>
<td>Myelodysplastic syndrome/myelofibrosis, No. (%)</td>
<td>1 (1)</td>
<td>2 (2)</td>
<td></td>
</tr>
<tr>
<td>Chronic myeloid leukemia, No. (%)</td>
<td>4 (4)</td>
<td>4 (4)</td>
<td></td>
</tr>
<tr>
<td>Chronic lymphocytic leukemia, No. (%)</td>
<td>7 (7)</td>
<td>6 (7)</td>
<td></td>
</tr>
<tr>
<td>Months since diagnosis, median (IQR)</td>
<td>13 (3.2-40)</td>
<td>8.7 (2.0-24)</td>
<td>.19</td>
</tr>
<tr>
<td>Allogeneic SCT, No. (%)</td>
<td>40 (38)</td>
<td>33 (36)</td>
<td>.79</td>
</tr>
<tr>
<td>SCT complication, No. (%)</td>
<td>17 (16)</td>
<td>16 (18)</td>
<td>.40</td>
</tr>
<tr>
<td>Days since SCT, median (IQR)</td>
<td>77 (31-217)</td>
<td>88 (18-201)</td>
<td>.91</td>
</tr>
<tr>
<td>Chemotherapy in previous 2 months, No. (%)</td>
<td>79 (75)</td>
<td>64 (70)</td>
<td>.52</td>
</tr>
<tr>
<td>Neutrophils &lt; 500μL on ICU admission, No. (%)</td>
<td>43 (41)</td>
<td>39 (43)</td>
<td>.88</td>
</tr>
<tr>
<td>Poor performance status, No. (%)</td>
<td>16 (15)</td>
<td>11 (12)</td>
<td>.52</td>
</tr>
<tr>
<td>Relapsed/progressive disease, No. (%)</td>
<td>65 (62)</td>
<td>39 (43)</td>
<td>.008</td>
</tr>
<tr>
<td><strong>Other chronic diseases, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung disease</td>
<td>14 (13)</td>
<td>15 (16)</td>
<td>.51</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>26 (25)</td>
<td>24 (26)</td>
<td>.80</td>
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<tr>
<td>Diabetes</td>
<td>25 (24)</td>
<td>23 (25)</td>
<td>.81</td>
</tr>
<tr>
<td>Vasoactive agents, No. (%)</td>
<td>28 (27)</td>
<td>20 (22)</td>
<td>.45</td>
</tr>
<tr>
<td>Additional malignant tumor</td>
<td>10 (10)</td>
<td>9 (10)</td>
<td>.93</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>10 (10)</td>
<td>12 (13)</td>
<td>.42</td>
</tr>
<tr>
<td>Deep venous thrombosis/pulmonary embolus</td>
<td>7 (7)</td>
<td>5 (5)</td>
<td>.78</td>
</tr>
<tr>
<td>Autoimmune disease</td>
<td>1 (1)</td>
<td>5 (5)</td>
<td>.10</td>
</tr>
<tr>
<td>Liver disease</td>
<td>5 (5)</td>
<td>7 (8)</td>
<td>.55</td>
</tr>
<tr>
<td>Sleep-disordered breathing ICU</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ICU</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days from hospital admission to ICU admission, median (IQR)</td>
<td>4 (0-14)</td>
<td>1 (0-10)</td>
<td>.02</td>
</tr>
<tr>
<td>ICU length of stay, median (IQR)</td>
<td>5 (1-10)</td>
<td>4 (2-9)</td>
<td>.77</td>
</tr>
<tr>
<td>Vasoactive agents, No. (%)</td>
<td>65 (62)</td>
<td>39 (43)</td>
<td>.01</td>
</tr>
<tr>
<td>Acute renal replacement therapy, No. (%)</td>
<td>20 (19)</td>
<td>9 (10)</td>
<td>.11</td>
</tr>
<tr>
<td>Invasive mechanical ventilation, No. (%)</td>
<td>71 (68)</td>
<td>26 (29)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Ventilator days, median (IQR)</td>
<td>1 (0-5)</td>
<td>0 (0-2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SOFA score, median (IQR)</td>
<td>9 (7-13)</td>
<td>7 (4-9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SOFA-HM score, median (IQR)</td>
<td>10 (8-15)</td>
<td>7 (4-11)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>APACHE II score, median (IQR)</td>
<td>26 (22-31)</td>
<td>21 (18-29)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit; IQR, interquartile range; SCT, stem cell transplant; SOFA, Sequential Organ Failure Assessment; SOFA-HM, Sequential Organ Failure Assessment–hematologic malignant tumor.

### Table 7
**Multivariable model for the 196 patients in the validation cohort**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOFA-HM score</td>
<td>1.21</td>
<td>1.12-1.30</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Age</td>
<td>1.03</td>
<td>1.00-1.05</td>
<td>.02</td>
</tr>
<tr>
<td>Days from admission to hospital to admission to intensive care unit&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.03</td>
<td>1.00-1.06</td>
<td>.03</td>
</tr>
</tbody>
</table>

Abbreviation: SOFA-HM, Sequential Organ Failure Assessment–hematologic malignant tumor.

<sup>a</sup> The interaction term between SOFA-HM and days from admission to the hospital to admission to the intensive care unit was nonsignificant (P=.58) and was not included in the model.
REFERENCES


To purchase electronic or print reprints, contact American Association of Critical-Care Nurses, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 899-1712 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
Background  Barriers to recruiting and retaining acutely ill older adults in clinical research include complexity of illness, fatigue, and early discharge.

Objective  To describe recruitment and retention challenges of examining cognitive dysfunction in older adults hospitalized for acute heart failure.

Methods  An examination of the reasons for recruitment and retention issues within an acute care, university-affiliated health care system.

Results  Sixty-two patients refused to participate for a variety of reasons; 11 were ineligible, and 27 participants who completed initial data collection refused to participate further because they were too tired, were being discharged on the day of data collection, or were discharged before the next data collection day.

Conclusions  Multiple barriers to the recruitment and retention of older adults hospitalized for acute heart failure were identified. Strategies are needed to augment recruitment and retention efforts, including expanding the number of data collection sites and allocating sufficient support resources. (American Journal of Critical Care. 2016;25:418-421)
Recruiting and retaining older adults (≥ age 65) in clinical research can be challenging, especially for older adults hospitalized in a critical care unit. Barriers to participation by community-dwelling older adults with chronic heart failure in research studies have been described, but the barriers to recruiting and retaining older adults hospitalized for acute heart failure have not been described.

Lack of family availability for consent and family members’ lack of willingness to provide consent are recruitment issues for critically ill patients, whereas complexity of illness, fatigue, and early discharge are challenges to studying acutely ill hospitalized older adults. Descriptions of the challenges of recruiting and retaining older adults hospitalized for acute heart failure are lacking, even though heart failure accounts for more than 1 million hospital admissions annually. To begin to address this knowledge gap, a description of the recruitment and retention challenges we faced and the subsequent strategies we used successfully to examine cognitive dysfunction in 53 older adults hospitalized for acute heart failure are described.

Methods

Briefly, we measured the relationship between acute heart failure symptoms and cognitive dysfunction and 30-day rehospitalization for acute heart failure in elderly patients hospitalized for acute heart failure. Computerized neuropsychological tests were used to measure cognitive function. Older adults who had more and worse symptoms of heart failure had decreased cognitive function accuracy and speed in attention and memory, but cognitive function was not predictive of 30-day readmission for acute heart failure.

Data were collected 3 days per week on acute inpatient units of a Midwestern university-affiliated health system that annually treats more than 800 patients with acute heart failure. Using the daily census and study inclusion/exclusion criteria, unit-based nurse screeners trained by the study team approached potential participants regarding their interest and willingness to meet with the study team regarding their possible participation. Nurse screeners forwarded the contact information of interested participants to the study team. Members of the study team then approached the potential participants, explained the purpose of the study, verified the patient’s eligibility (inclusion/exclusion criteria plus Mini–Mental State Examination [MMSE] score ≥ 21), addressed study-related questions, obtained consent, and collected all study-related data. Participants who scored less than 21 on the MMSE were thanked for their interest but summarily excluded from participating in the study.

To minimize the effect of fatigue resulting from morning care, diagnostic tests, and procedures on the assessment of cognitive function, cognitive function data were collected between 12 noon and 4 PM. Rest breaks were offered as needed. Consent procedures took between 5 and 30 minutes, depending on the number of participant questions and whether or not we read the informed consent document to participants. Completing the questionnaires about symptoms of heart failure and computerized cognitive tests, which included laptop practice and familiarization time, took approximately 15 minutes. All questionnaires were loaded onto the computer and read to participants to reduce patient fatigue, minimize missing data, and standardize data collection. The computer approach was an effective data collection method, and all participants were able to respond.

Recruitment and Retention Issues

Several recruitment and retention issues prevented the collection of questionnaire and cognitive function data beyond one time point and limited the sample size. Sixty-two patients with acute heart failure, who had voiced interest to study screeners, refused to participate when approached by the study screeners.

About the Authors

Cynthia Arslanian-Engoren is an associate professor and Donna Algase is a professor emerita, University of Michigan School of Nursing, Ann Arbor, Michigan. Amanda Schuh is a psychiatric nurse practitioner, Mayo Clinic Health System, Mankato, Minnesota. Bruno J. Giordani is a professor, Ambulatory Psychiatry, University of Michigan, Ann Arbor, Michigan. Corinne Lee is an educational nurse specialist, Professional Development and Education, University of Michigan Health Systems, Ann Arbor, Michigan. Debra K. Moser is a professor, University of Kentucky College of Nursing, Lexington, Kentucky.

Corresponding author: Cynthia Arslanian-Engoren, RN, PhD, ACNS-BC, FAHA, FAAN, University of Michigan, School of Nursing, 400 North Ingalls, Room 2176, Ann Arbor, MI 48109 (e-mail: cmae@umich.edu).
team, often before an explanation of the study had been provided. More than half (n = 35) of these 62 patients refused without a specific reason. Reasons provided ranged from being too tired to the length of the 8-page informed consent form. Eleven potential participants were ineligible because they were in isolation (n = 6), hemodynamically unstable (n = 2), off the unit (n = 2), or sedated (n = 1) when the study team arrived (see Table).

Additional issues adversely affected the retention of 27 participants who had completed an initial data collection session. Three of those participants refused to participate further because they were too tired (n = 1), too sick (n = 1), or did not want to participate (n = 1); 6 other participants did not provide a specific reason for their refusal. The remaining 18 participants refused because they were being discharged on the day of data collection or had already been discharged before the next, scheduled data collection day.

To compensate for these issues and to augment recruitment, we implemented several strategies. One strategy was that unit-based staff nurse screeners were asked to confirm with potential participants their willingness to meet with a study team member before alerting the study team. A second strategy was to increase the number of recruitment units from 1 to 3, and a third strategy was to continue recruitment efforts for an additional 12 weeks. After 3 months without any new participants, recruitment was halted.

Discussion

Examining cognitive dysfunction and symptoms of acute heart failure in hospitalized older adults proved to be quite challenging. Multiple recruitment and retention barriers were encountered. This was especially noteworthy, given the large number of potential participants treated at the data collection site and deliberate use of nurses who routinely care for patients with acute heart failure to screen and recruit potential participants, as recommended.

Several system and individual factors hampered our ability to recruit and retain participants. One was that the mean length of stay for patients with acute heart failure is between 5 and 6 days.12,13 This length of stay contributed to a narrow recruitment and retention window, once patients’ conditions were hemodynamically stable. Another factor was the presence of symptoms of acute heart failure and a high number of nonspecific reasons for refusal. Patients most often indicated that they were too tired or too sick to participate. Approaching patients again after their symptoms have subsided could help to increase recruitment. A third issue was the length of the informed consent form. Although several older adults complained about the length of the 8-page consent document, only 1 actually refused to participate because of it. Because lengthy informed consent documents can add to the lack of interest and prevent potential participants from considering participation,14 we recommend that the length of the consent forms be reduced for low-risk studies.

Recommendations for future investigations include devoting adequate resources (personnel, time, and budgetary) to maximize recruitment6 and providing incentives4 or tokens of appreciation to encourage longitudinal participation of older adults.2 We recommend that a dedicated recruiter be available 7 days a week (at least 6-8 hours a day). The recruiter should be an expert in developing relationships with people and an expert communicator, to engage with staff on the heart failure unit on a person-to-person level before launching into the study. Developing relationships with unit-based nurse and/or physician champions who would talk to patients about the importance of the project may increase recruitment. To encourage participation and to maximize recruitment, we recommend that family members be included and educated regarding study procedures to encourage participation1 and that nurse screeners accompany study team members into patients’ rooms to provide initial introductions of study team members to interested older adults.

Last, to elucidate the underlying reasons for unexplained refusals, we recommend that data collectors be trained on how to gently ask about specific reasons and to offer options to address issues that limit participation.

### Table: Reasons for initial refusal to participate

<table>
<thead>
<tr>
<th>Reason</th>
<th>No. of refusals</th>
</tr>
</thead>
<tbody>
<tr>
<td>No specific reason given</td>
<td>35</td>
</tr>
<tr>
<td>Ineligible</td>
<td>11</td>
</tr>
<tr>
<td>Too tired</td>
<td>4</td>
</tr>
<tr>
<td>Not interested today</td>
<td>4</td>
</tr>
<tr>
<td>Being discharged</td>
<td>3</td>
</tr>
<tr>
<td>Too sick</td>
<td>2</td>
</tr>
<tr>
<td>Unable to see computer screen well enough</td>
<td>1</td>
</tr>
<tr>
<td>Physically limited by arthritis</td>
<td>1</td>
</tr>
<tr>
<td>Length of consent form (8 pages)</td>
<td>1</td>
</tr>
<tr>
<td>Total number of potential participants who refused</td>
<td>62</td>
</tr>
</tbody>
</table>
Summary

Multiple barriers to the recruitment and retention of older adults hospitalized for acute heart failure were identified. Strategies are needed to augment recruitment and retention efforts, including nurse and physician champions, reducing the length of voluminous informed consent documents, expanding the number of data collection sites, and allocating sufficient financial and human resources to support efforts to improve recruitment and retention of older adults hospitalized for acute heart failure.

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REFERENCES

To purchase electronic or print reprints, contact American Association of Critical-Care Nurses, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 899-1712 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
How do we know that the care we provide is going to result in the best outcomes? Traditional practices in critical care, such as keeping patients in bed or using saline to suction endotracheal tubes, are debunked by existing research, offering the lesson that what seems right may actually contribute to worse outcomes. Feeling confident about our care is not always easy. At times, there is no evidence to guide us. The best evidence comes when bedside nurse champions collaborate with researchers and encourage staff and patient participation in projects. Still, recruiting critically ill patients into research projects is challenging as they are focused on their recovery and generating new information is not their priority.

The absence of concrete answers about best practices can be frustrating, however an appreciation that nursing practice is ever evolving also offers opportunities. There may be solutions no one has yet studied that are promising and worth trying. Large-scale clinical research studies require time, money, and other resources, but smaller studies that are specific to a particular clinical setting and therefore produce results applicable to that setting, are feasible. Nurses who participate in such projects often experience renewed professional engagement and job satisfaction.

Here’s what you can do:

- Remain curious about best practice. Ask questions and look for answers.
- Look for creative solutions if there is no evidence to guide you and consider developing a case study about the outcomes.
- Discuss practice questions with other members of your health care team and see if they are aware of resources, or have faced a similar problem.
- Consider partnering with faculty at a school of nursing, advance practice nurses in your institution, or nurses seeking projects for graduate school programs.
- Seek support from your hospital administration to conduct clinical research that may help answer the question. Be ready to describe the benefits that the project offers to the institution.

Other helpful resources:

- AACN Practice Alerts, CSI Innovation Database, and Searching for Evidence Toolkit, available online at aacn.org
Background
In 2010, the incidence of prolonged mechanical ventilation (>24 hours) after isolated coronary artery bypass graft (CABG) surgery was 26.9% at the study site, The Ohio State University Wexner Medical Center, compared with the national like-hospital rate of 10.9%.

Objectives
To use the principles of lean management to reduce the incidence of prolonged mechanical ventilation and to assess the sustainability of that reduction over time.

Methods
A multidisciplinary prolonged ventilation task force conducted a gap analysis leading to 3 interventions: (1) a standardized extubation protocol, (2) dry erase boards in patients’ rooms to facilitate team communication, and (3) edits of the postoperative order set within the electronic health record. Outcomes of mechanical ventilation in CABG patients before and after the interventions are compared.

Results
All target outcomes changed significantly after the interventions, including a reduction in the median hours of initial mechanical ventilation (from 11.4 hours to 6.9 hours, \(P<.001\)). The percentage of patients reintubated did not increase (a decrease from 11.8% to 3.5% was not significant, \(P=.08\)). The rate of prolonged ventilation decreased from 29.4% to 8.8% (\(P=.004\)), and this reduction was sustained for 4 years after the interventions.

Conclusions
Success factors included the multidisciplinary task force and continual protocol reeducation among front-line staff. (American Journal of Critical Care. 2016;25:423-430)
An increase in the number of coronary artery bypass graft (CABG) surgeries performed in the United States and the increasing cost of health care have led to questions about the risk and costs of the perioperative support required after CABG surgery. Specifically, cardiac anesthesia has historically involved use of high-dose opioid anesthetics, committing the patient to a postoperative period of mechanical ventilation that increased both risk and cost. With the goal of facilitating early extubation (within 6 hours of surgery), Cheng and colleagues tested the use of 15 μg/kg of fentanyl versus 50 μg/kg of fentanyl. This new protocol reduced length of stay in both the intensive care unit (ICU) and the hospital and saved health care resources, lowering total costs per CABG surgery.

Follow-up studies demonstrated that early extubation—known as “fast track” cardiac anesthesia—does not pose additional risks, positioning early extubation as the standard of care in cardiac surgery. A 2011 American College of Cardiology guideline gave a class I recommendation for an anesthetic directed toward early postoperative extubation among low- to medium-risk CABG patients. In a meta-analysis of fast-track cardiac practices, researchers reported that although anesthetic management affects the ability to allow early extubation, an extubation protocol was pivotal, thus highlighting the importance of the work processes within a cardiac surgery unit.

Given this finding, quality improvement (QI) processes play an important role as hospitals and health systems aspire to comply with current “fast-tracking” guidelines. “Lean management,” a key QI process, was first used to describe the Toyota business model. The Toyota Production System was a model developed to eliminate waste and variability. A key component of lean management is holding every individual responsible and accountable to use tools that will reduce variability in the work process. Lean management has been used in many areas of medicine, including critical care.

In this study, we applied the principles of lean management to a cardiac surgery unit within a large academic medical center in order to decrease both the incidence of prolonged mechanical ventilation and the median time to extubation following CABG. This QI process was implemented as a response to the findings of an audit conducted by the prolonged ventilation task force (details of the task force provided later). Within our health system between 2008 and 2010, the incidence of prolonged mechanical ventilation (intubation for >24 hours) for isolated CABG was 26.9%, compared with the like-hospital rate of 10.9% for the same time period. The objectives of this study were to reduce this rate to or below the mean national rate for like hospitals and to assess the sustainability of that reduction over time.

**Methods**

This study employed A3 thinking, which is a consensus building process that uses a succinct visual communication tool to guide project participants. Within the A3 model, we conducted a gap analysis with the goal of comparing best practices with the processes in place at the organization and identifying the gaps between current performance and best practices. The QI program was implemented in 2010, and primary outcome measures were compared in 2 groups of CABG patients, 6 months before and 6 months after the intervention. Sustainability of the main outcome measure, prolonged mechanical ventilation, was tracked for 4 years after the intervention.
Setting
This study was implemented in the Division of Cardiac Surgery at The Ohio State University Wexner Medical Center. The Division of Cardiac Surgery provides care for patients within a dedicated heart hospital where 6 surgeons performed 2596 cardiac procedures in fiscal year 2014, qualifying the division as the busiest cardiac surgery program in the region.

Prolonged Ventilation Task Force
Formed in 2010, the task force included multidisciplinary professionals: cardiac surgeons, intensivists, anesthesiologists, nurse administrators, advanced practice nurses, respiratory therapists, pharmacists, and perfusionists. It was championed by the chief quality and patient safety officer and led by members of the Office of Quality and Patient Safety. The task force charter included 2 goals for patients undergoing isolated CABG: (1) within 1 year, achieve prolonged ventilation rates that are at or below the national Society of Thoracic Surgeons (STS) like-hospital benchmark of 12%, (2) achieve a median initial ventilation time of 7.6 hours (the STS benchmark) within the same time frame. “Like hospitals” are those with a similar bed capacity, and the benchmark is based on the median rate among those like hospitals.

Gap Analysis
Three types of data collection informed the gap analysis: retrospective chart reviews, interviews with stakeholders, and focus groups. The task force conducted retrospective chart reviews of patients who met the criteria for prolonged mechanical ventilation. A root-cause analysis was conducted for each case. Root-cause variables included lack of communication between team members, redundant and excessive analgesic medications within postoperative order sets that led to variation in ordering practices, and unstandardized extubation practices and goals. Specifically, the decision to pursue early extubation was an unstandardized and independent decision-making process supported by minimally structured clinical management by each member of the team instead of a standardized process encouraging early extubation.

Interviews and focus groups were an additional element of the gap analysis. Members of the task force conducted 1-on-1 interviews with nurses, respiratory therapists, physicians, and anesthesiologists who work on the cardiac unit. Interviewees were asked about their work processes and their perspectives on questions such as “why are some patients on vents for so long?” Similar topics were discussed in the style of focus groups during staff meetings. Information collected from the interviews and focus groups supported the prevalence of these root causes and provided contextual detail related to the situations in which these root causes occur.

Interventions
Upon completion of the gap analysis, the multidisciplinary task force developed 3 interventions aimed at addressing the identified root causes. These included (1) the development of an extubation protocol to standardize extubation practices, (2) the introduction of dry erase boards in patients’ rooms to facilitate team communication, and (3) edits of the postoperative order set within the electronic medical record to reduce medication variation and redundancy in order to facilitate appropriate drug utilization.

The extubation protocol was developed with the goal of setting early extubation as the standard and the decision to delay extubation as the exception. Figure 1 is the cardiothoracic surgery ventilator weaning and extubation protocol, which consists of a decision tree from arrival in the ICU until extubation that requires reassessment of patients every 30 minutes and a specific weaning process once weaning is initiated. The nurse and the respiratory therapist could follow this protocol without the need for additional physician orders.

The second intervention was the installation of dry erase boards in each patient’s room on the cardiac unit to facilitate communication, both among the care team and during handoffs across teams. During handoffs, the operating room team could use the board to write extubation goals, concerns, and notes to the receiving team. Team communication breakdowns were identified as a root cause of prolonged extubation because respiratory therapists and other team members did not have a method to easily identify and contact the patient’s nurse. The dry erase board addressed this problem with space for the nurse’s name and phone number to facilitate contact between the nurse and other team members.

A third intervention was developed in response to the gap analysis finding that postoperative order sets in the electronic health record allowed redundant and excessive use of analgesics and sedatives, leading to unnecessary variability in ordering and administration. Specifically, with respect to options for analgesia, the order set included multiple parenteral (fentanyl, morphine, hydromorphone) and oral agents (oxycodone/acetaminophen, hydrocodone/acetaminophen, acetaminophen). The order set was edited to reduce redundancy by limiting
Upon patient arrival to patient care unit:
- Obtain initial ventilator settings from ICU intensivist or place patient on 8 mL/kg IBW
- Mode: SIMV pressure-regulated volume control (VC+) or SIMV Volume Control

Determine goal extubation time from surgeon or intensivist

After 20 minutes on settings obtain ABG

Is pH ≥ 7.34? or PaO₂ ≥ 120 mm Hg?

YES

Begin weaning O₂:
- Wean O₂ from 100% down to 40% as tolerated keeping SpO₂ ≥ 93%.
- If PEEP is > 8 cm H₂O, obtain MD order to wean PEEP.

WEAN RATE AS TOLERATED:
- Wean SIMV rate by 4 or more BPM Q 30min to Spontaneous Mode (PEEP = 5 and PS = 10).
- If patient is awake, cooperative (RASS +1 to -1) and breathing < 25 BPM, vent rate may be reduced to Spontaneous Mode more rapidly.

Reassess ABG in 30 min

NO

Correct for respiratory acidosis by increasing respiratory rate and obtain order to increase PEEP if indicated.

If patient is hemodynamically stable 5 hours post-op, place patient on Spontaneous Mode.

Document in Adult Vent flow sheet
- Assess for tolerance

After 30 min on Spontaneous Mode, obtain ABG and weaning parameters

Do all of the following exist?
- pH ≥ 7.34, PaO₂ ≥ SpO₂ ≥ 93%
- Vt ≥ 5 mL/kg, VC ≥ 10 mL/kg, NIF ≥ 25, f/Vt ≤ 100

YES

Extubate and place on 6 L NC

Obtain ABG 30-60 min post extubation

NO

Figure 1  Cardiothoracic surgery ventilator weaning and extubation protocol.

Abbreviations: ABG, arterial blood gases; BPM, breaths per minute; f, frequency; IBW, intake body weight; ICU, intensive care unit; MD, physician; NC, nasal cannula; NIF, negative inspiratory force; O₂, oxygen; PEEP, positive end-expiratory pressure; post-op, post-operatively; PS, pressure support; Q, every; RASS, Richmond Agitation-Sedation Scale; SIMV, synchronized intermittent mandatory ventilation; SpO₂, oxygen saturation shown by pulse oximetry; vent, ventilator; Vt, tidal volume; VC, volume control.

Courtesy The Ohio State University Wexner Medical Center, Columbus, Ohio.
standard orders to include 1 parenteral agent (hydromorphone) and 1 oral agent (oxycodone/acetaminophen) to facilitate availability of relatively short-acting agents that are minimally affected by variable end-organ function across the population.

**Education and Feedback**

The 3 interventions were implemented with rigorous, and multimodal, staff education. Initial education was conducted informally through 1-on-1 discussions between members of the task force and staff from their respective disciplines; across multiple shifts both on the unit floor and during break room discussions. Additionally, members of the task force attended staff meetings to provide detailed instructions for the incorporation of the extubation protocol and the new whiteboard communication process into the current unit workflow. During these conversations, the task force was careful to frame the interventions as the work product of the extensive staff engagement that occurred during the gap analysis, in addition to highlighting the multidisciplinary nature of the task force itself.

Additional educational outreach specific to the extubation protocol included e-mailing staff to provide the protocol and a “go-live” date, and updating the nurses’ bedside references so that the new protocol would be easily accessible at the patients’ bedside. During the initial 6-month implementation period and continuing during the maintenance period, staff members were provided feedback on the outcomes of interest. At monthly meetings of nurses and respiratory therapists, a task force representative shared updates on the number of cases of prolonged ventilation and the current mean time to initial extubation. An opportunity also was provided to discuss the implementation of the interventions and troubleshoot barriers as they arose.

**Data Collection**

The Division of Cardiac Surgery participates in and reports to the STS national database—established in 1989 as a tool for national-level quality improvement and patient safety among cardiothoracic surgeons. In order to report to the national database, the division maintains an institution-level STS adult cardiac surgery database, comanaged with the Office of Quality and Patient Safety. This database includes patients’ demographic data, procedural data, and perioperative outcomes that are abstracted and entered into the STS database from the medical center’s electronic medical records. Access to data for this article was approved via an institutional quality data release, and the Health Insurance Portability and Accountability Act of 1996 (HIPPA) regulations were followed at all times in order to maintain the confidentiality of patients’ personal information.

**Outcomes and Analysis**

Patients who had CABG surgery performed during the 6 months before the quality improvement process (January through June 2010) were categorized as group 1. Patients who had surgery performed in the 6 months after implementation of the quality improvement process (January through June 2011) were categorized as group 2. Significant differences in demographic and health status variables between these groups were calculated by using χ² tests to detect significant differences in the distribution of the variables across study groups.

Outcomes included the median number of hours of mechanical ventilation after CABG surgery, termed initial mechanical ventilation. The percentage of patients undergoing early extubation was also calculated, with early extubation defined as occurring within 6 hours of ICU arrival. Prolonged mechanical ventilation, defined as initial mechanical ventilation for more than 24 hours, was calculated as a percentage of patients in each group. The proportion of patients reintubated was collected. The outcome variables were compared between groups by using t tests of a significant difference in means for the continuous variables and χ² tests for the categorical variables. Multivariate modeling was not conducted because the 2 groups did not differ significantly on any measured variables. Analyses were conducted by using SPSS version 20-22 (SPSS Inc).

**Results**

The Division of Cardiac Surgery performed 68 CABG operations in the 6 months before the interventions (group 1) and 58 in the 6 months after the interventions (group 2). Table 1 presents demographic and health status variables that may be associated with differences in intubation rates, including hypertension, dyslipidemia, chronic lung disease, the urgency of the surgery, and the presence of an intra-aortic balloon pump. These variables did not differ significantly (P < .05) between the groups. Other nonsignificant variables that occurred in less than 5% of our sample included previous cardiac surgery, emergent salvage, and cardiogenic shock.

All target outcomes changed significantly from before to after the interventions (Table 2), including a significant reduction in the median hours of initial mechanical ventilation (P < .001). The median number
of hours of initial mechanical ventilation was 6.9 after the intervention, below the STS benchmark of 7.6 hours. The percentage of patients extubated early increased from 19% before the interventions to 41% after the interventions ($P = .01$) and the percentage reintubated did not increase (there was a nonsignificant decrease from 12% to 4%, $P = .08$). The rate of prolonged mechanical ventilation also decreased, from 29% to 9% ($P = .004$).

Figure 2 presents the rate of prolonged mechanical ventilation 6 months before the interventions (first quarter of 2010) until the third quarter of 2014, which is 4 years after the interventions. Within 3 months of the implementation of the interventions, the rate of prolonged mechanical ventilation was below the STS’s mean rate for like hospitals and stayed around the STS mean for the following 2 years. In 2013, the rate started to increase and the task force members turned their attention to this issue, which corresponded to a sharp decrease back to less than the STS mean.

**Discussion**

This QI project was successful at reaching the goals set by the prolonged ventilation task force. Implementation of a 3-part intervention—an extubation protocol, dry erase communication boards in patients’ rooms, and a standardized postoperative medication order set—led to a decrease in the rate of prolonged ventilation after CABG similar to the STS’s mean for like hospitals and sustained success across subsequent years. Although it was not an original goal of the task force, another finding of note is the significant increase in the rate of early extubation (extubation <6 hours after ICU arrival). The percentage of patients reintubated did not increase after the interventions, providing evidence that the extubation protocol did not lead to premature extubation of patients.

This success is similar to that seen in other applications of lean thinking to health care, most commonly in surgery and emergency departments. However, in a 2015 systematic review of use of lean techniques in health care, researchers reported positive but not conclusive evidence of improved quality and safety outcomes. These inconclusive results may be due in part to a need to delineate what implementation strategies led to the success of QI initiatives. One element critical to success was the application of a thorough gap analysis. This analysis identified root causes of the high rate of prolonged mechanical ventilation, enabling the creation of interventions that were tailored to the specific causes of the problem.

Another element of success was the engagement of the key disciplines involved in the process on the

### Table 1
Demographic and health status variables for isolated coronary artery bypass surgery patients before and after intervention

<table>
<thead>
<tr>
<th>Variable</th>
<th>Before intervention (n = 68)</th>
<th>After intervention (n = 58)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean, y</td>
<td>64</td>
<td>63</td>
</tr>
<tr>
<td>Female</td>
<td>12 (18)</td>
<td>15 (26)</td>
</tr>
<tr>
<td>Body mass index$^b &gt; 30$</td>
<td>34 (50)</td>
<td>26 (45)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>64 (94)</td>
<td>54 (93)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>65 (96)</td>
<td>57 (98)</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>22 (32)</td>
<td>16 (28)</td>
</tr>
<tr>
<td>Elective surgery</td>
<td>25 (37)</td>
<td>22 (38)</td>
</tr>
<tr>
<td>Urgent surgery</td>
<td>41 (60)</td>
<td>34 (59)</td>
</tr>
<tr>
<td>Emergent surgery</td>
<td>2 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Intra-aortic balloon pump</td>
<td>11 (16)</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Off-pump bypass surgery</td>
<td>18 (26)</td>
<td>21 (36)</td>
</tr>
</tbody>
</table>

$^a$ No significant differences between groups were found at $P$ less than .05.

$^b$ Calculated as weight in kilograms divided by height in meters squared.

### Table 2
Outcomes related to mechanical ventilation in coronary artery bypass graft surgery patients before and after the intervention

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Before intervention (n = 68)</th>
<th>After intervention (n = 58)</th>
<th>$P^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours of initial mechanical ventilation, median</td>
<td>11.4</td>
<td>6.9</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Early extubation (initial mechanical ventilation &lt; 6 h), %</td>
<td>19</td>
<td>41</td>
<td>.01</td>
</tr>
<tr>
<td>Reintubated, %</td>
<td>12</td>
<td>4</td>
<td>.08</td>
</tr>
<tr>
<td>Prolonged mechanical ventilation (&gt; 24 h), %</td>
<td>29</td>
<td>9</td>
<td>.004</td>
</tr>
</tbody>
</table>

$^a$ Significant difference at $P$ less than .05.
The task force was multidisciplinary, including all professional groups that care for CABG patients in the cardiac unit. This multidisciplinary approach is a key element of lean management implementation and allowed the team involved in patient care to engage in quality improvement and find solutions to provide the highest standard of care. The principles of lean management hold each member of the team accountable for creating and using tools, in this case the 3 interventions, to reduce variability in the work process. The integration of staff at all levels in the implementation process through education and feedback facilitated buy-in and fidelity to the 3 interventions. Specifically, the real-time assessment and feedback of patients who were extubated in a timely manner allowed rapid assessment of failure modes and modifications to facilitate protocol fidelity.

A unique element of this study is the exploration of sustainability years after initial implementation. Figure 2 also shows a slowly increasing rate of prolonged mechanical ventilation in 2013, almost to preintervention levels. When stakeholders from the task force were made aware of this increase, a flurry of discussion ensued and attention was paid to the elements of the initial QI intervention. The increasing rate required reengagement of team members, many of whom were new to the organization and unaware of the protocol. This situation revealed an opportunity to develop a process by which front-line staff members, both new and old, are continuously reeducated on patient care strategies so that current and new protocols are used. Subsequent to the implementation of this reeducation process, the rate returned to less than the STS’s mean for like hospitals.

Therefore, the important addition of this study to the literature is the identification of sustainability success factors. Our findings support many of the framework elements for supportive QI conditions recently proposed by Matthaeus-Kraemer and colleagues, including the importance of multidisciplinary members of a dedicated QI team, the engagement of front-line staff in the dissemination process, external benchmarks, and administrative support. The present study adds to this framework by considering the process of planning before implementation of interventions and long-term sustainability.

**Conclusions**

A lean management intervention to standardize workflow protocols and facilitate team communication achieved significant and sustained success. This sustainability across 4 years can be attributed to the multidisciplinary task force charged with addressing this issue and the continued focus on the engagement and education of front-line staff. The details provided in this article can help to guide other critical care medicine departments in their quality improvement processes.

**FINANCIAL DISCLOSURES**

None reported.

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This article has been designated for CE contact hour(s). The evaluation tests your knowledge of the following objectives:

1. Examine a lean quality improvement intervention to reduce prolonged ventilation after coronary artery bypass graft.
2. Describe the quality improvement processes and tools used to explore the problem and develop interventions.
3. Identify success factors critical to the sustainability of this quality improvement intervention.

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Organizational and Teamwork Factors of Tele–Intensive Care Units


Background  Use of tele–intensive care involves organizational and teamwork factors across geographic locations. This situation adds to the complexity of collaboration in providing quality patient-centered care.

Objective  To evaluate cross-agency teamwork of health care professionals caring for patients in tele–intensive care units in rural and urban regions.

Methods  A national qualitative study was conducted in 3 US geographic regions with tele–intensive care programs. Discussions and interviews were held with key participants during site visits at 3 hub sites (specialist services location) and 8 rural spoke sites (patient location). The effects of communication and culture between the hub team and the spoke team on use of the services and effectiveness of care were evaluated.

Results  A total of 34 participants were interviewed. Specific organizational and teamwork factors significantly affect the functionality of a tele–intensive care unit. Key operational and cultural barriers that limit the benefits of the units include unrealistic expectations about operational capabilities, lack of trust, poorly defined leadership, and a lack of communication policies. Potential solutions include education on spoke facility resources, clearly defined expectations and role reversal education, team-building activities, and feedback mechanisms to share concerns, successes, and suggestions.

Conclusion  Proper administration and attention to important cultural and teamwork factors are essential to making tele–intensive care units effective, practical, and sustainable. (American Journal of Critical Care. 2016;25:431-439)
Unsuccessful collaboration in the ICU has been linked to poor satisfaction of patients and patients’ families, higher costs, poor retention of nurses, and below-optimal patient outcomes and safety. Communication problems were not limited to the poor transmission of information; they also involved role ambiguity, a poor understanding of the other teams’ working conditions and environment, and lack of a unified effort to provide care for patients. Creating an effective and well-functioning interdisciplinary team is particularly difficult and is located in an urban community. Each location has its own resources, policies, clinical practices, and organizational cultures. Furthermore, the relationships can be more complex if the teams reside in geographically distant locations and have different communication standards, cultural norms, and teamwork structure. These factors can have a major impact on collaboration, working conditions and environment, and lack of a unified effort to provide care for patients.

Creating an effective and well-functioning interdisciplinary team is crucial to the success of a tele-ICU program.

About the Authors
Michael S. Wilkes is a professor, Department of Internal Medicine and director of Global Health, and James P. Marcin is a professor and division chief, Pediatric Critical Care, Department of Pediatrics, University of California, Davis School of Medicine, Sacramento, California. Lois A. Ritter is a research manager, WMRA Inc, Sacramento, California. Sherilyn Pruitt is director, Office of Programs and Engagement in the Office of the National Coordinator for Health Information Technology, US Department of Health and Human Services, Washington, DC.

Corresponding author: James P. Marcin, MD, MPH, Professor and Division Chief, Pediatric Critical Care, Department of Pediatrics, 2516 Stockton Blvd, Sacramento, CA 95817 (e-mail: jpmarcin@ucdavis.edu).

Methods

Study Design

The study sample consisted of 3 US tele-ICU programs in 3 geographic regions. The study approach involved a common conceptual framework that included a core set of variables and questions and their impact on common outcome variables that were operationally defined in the same way across sites. The design allowed flexibility to assess site-specific and common variables. Each site needed an evaluation design that achieved internal validity, and the 3 sites provided multiple replications of the results to increase the external validity of the findings. For example, results that were significant for all 3 sites can be construed as particularly strong. We also were able to assess which factors within a particular site were responsible for within-site results but were not found or replicated across other sites.

Site Selection and Recruitment

Sites were selected according to the following criteria: each network had 3 or more spoke sites located in federally designated rural areas; networks used the Philips VISICU tele-ICU system to eliminate
variability introduced by different technologies; networks had been fully operational for at least 2 years; and programs operated in hospitals that were nonfederal. Potential sites were identified via literature and website searches. If sites met the criteria, the tele-ICU program was contacted to request participation in the study. The 3 qualifying sites that were approached all agreed to participate. The study design and consent forms were reviewed and approved by the institutional review board at Walter R. McDonald & Associates, Inc (now WRMA, Inc) and reviewed by all participating programs before site visits, interviews and data collection.

After approval by the review board, administrators, tele-ICU managers, and medical directors of potential hub sites were sent an e-mail about the study. Follow-up telephone calls provided details about the study. Three rural affiliate hospitals per hub site served as the study spoke sites. One tele-ICU program was connected to 3 spoke hospitals, all of which were rural (3 of 3 selected); another program had 9 rural spoke hospitals (3 of 9 selected); and the third had 19 rural spoke hospitals (3 of 19 selected). On the basis of the research team’s requests for a mix of critical access and prospective payment system hospitals, a range in the length of time of operation, and ICU bed occupancy rates, the respective tele-ICU administrative leaders made recommendations on which spokes were most appropriate to be included in the study (Table 1). All of the spoke sites had tele-ICU coverage from noon to 7 AM.

Before the site visit, each facility was provided with materials that included a study overview, biographies of members of the site visit team, an explanation of data elements requested, a description of the data submission processes, and general site discussion topics. All interviewees signed an informed consent before the interview and remained entirely anonymous.

**Participant Interviews**

In-person meetings at the spoke and hub sites took place between August 2011 and March 2012 (Table 2). Interview participants included administrators, ICU nurses, and physicians from the rural spoke sites; administrators, tele-ICU nurses, and physicians from the hub site. Interview guides were developed for the type of site (hub or spoke) and type of health care professional (administrator, nurse, physician) and included questions such as the following: How are conflicts or disagreements in clinical opinions handled? What helps or hinders communication between the spoke and hub site teams? How has the communication with the hub or spoke site changed over time? How are conflicts or disagreements in opinion handled? Follow-up questions were asked, and the questions changed as the study progressed. At least 2 researchers participated in each interview. One interviewer participated in all 34 interviews; a research associate participated and took notes (2 research associates were engaged in the study). After data collection, the notes were transcribed by 1 of the research associates within 48 hours and then reviewed by the other interviewer to ensure accuracy. Discrepancies between the interviewers were resolved through discussions. When uncertainty persisted,

<table>
<thead>
<tr>
<th>Site</th>
<th>Payment system</th>
<th>Go-live date</th>
<th>No. of dedicated ICU beds</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Network 1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hub site 1</td>
<td></td>
<td>2005</td>
<td>NA</td>
</tr>
<tr>
<td>Spoke site 1A</td>
<td>Critical access hospital</td>
<td>2006</td>
<td>4</td>
</tr>
<tr>
<td>Spoke site 1B</td>
<td>Prospective payment system</td>
<td>2006</td>
<td>4</td>
</tr>
<tr>
<td>Spoke site 1C</td>
<td>Prospective payment system</td>
<td>2008</td>
<td>5</td>
</tr>
<tr>
<td><strong>Network 2</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hub site 2</td>
<td></td>
<td>2004</td>
<td>NA</td>
</tr>
<tr>
<td>Spoke site 2A</td>
<td>Critical access hospital</td>
<td>2006</td>
<td>1</td>
</tr>
<tr>
<td>Spoke site 2B</td>
<td>Critical access hospital</td>
<td>2005</td>
<td>4</td>
</tr>
<tr>
<td>Spoke site 2C</td>
<td>Critical access hospital</td>
<td>2005</td>
<td>0</td>
</tr>
<tr>
<td><strong>Network 3</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hub site 3</td>
<td></td>
<td>2004</td>
<td>NA</td>
</tr>
<tr>
<td>Spoke site 3A</td>
<td>Prospective payment system</td>
<td>2006</td>
<td>6</td>
</tr>
<tr>
<td>Spoke site 3B</td>
<td>Prospective payment system</td>
<td>2006</td>
<td>6</td>
</tr>
</tbody>
</table>

Abbreviation: ICU, intensive care unit; NA, not applicable.

| Table 2 |
| Number of interviews conducted by site and type of staff |

<table>
<thead>
<tr>
<th>Network</th>
<th>Administrator</th>
<th>Nurse</th>
<th>Physician</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hub</td>
<td>Spoke</td>
<td>Hub</td>
<td>Spoke</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>4</td>
<td>9</td>
<td>4</td>
<td>9</td>
</tr>
</tbody>
</table>

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clarification with the interviewee was sought via telephone and e-mail. The interview notes were then reviewed by the interviewees for accuracy. No inaccuracies were identified by the interviewees.

Data Analysis
The content analysis of the qualitative data was conducted by using ATLAS.ti, version 6, software (Scientific Software Development GmbH). The codes were inductively developed by the interviewees during a group discussion. The interview notes were then coded in ATLAS by 1 of the researchers. The other researchers who participated in the interviews reviewed the coded transcripts for interrater reliability. Associations between codes and groups (eg, networks, site type) were explored, and comparisons were made within and across groups. Pertinent quotations were identified and flagged.

Results
Spoke Hospitals
Of the 9 enrolled rural spoke sites, 1 withdrew from the study because of time and workload constraints. All 8 of the remaining spoke sites that participated were located in federally designated rural areas. Four of the spoke hospitals were critical access hospitals. The spoke hospitals were located in 4 different states. The participating rural spoke hospitals had 1 to 6 designated ICU beds. The distance between the hub and rural spoke sites ranged from 44 to 356 miles (70-570 km) for a mean of 94 miles (150 km). Among the spoke sites, 2 started with tele-ICU in 2005, 5 in 2006, and 1 in 2008.

Impact of Tele-ICU on Patient Care
A total of 34 clinicians and administrators participated in the interviews. The clinicians who used tele-ICU shared their personal stories and those of their patients. Benefits of tele-ICU, such as patients remaining close to the patients' families and spoke site nurses having assistance in the middle of the night, were reflected in staff members' recollections. This additional oversight that allowed patients to remain in their community was thought to be a major advance from the perspective of the clinicians and administrators from the rural spoke hospitals. The spoke site clinicians and administrators often mentioned that consultations with the hub site were helpful in determining if a patient's condition warranted referral to palliative care teams, transfer to a tertiary facility, or both. The clinicians thought that such clarification often enabled patients to end their lives in the patients' community near family and loved ones, a situation that was always valued by patients' family members.

Organizational and Teamwork Factors
A clear message that emerged from the interviews was that teamwork, communication, and cooperatively established tele-ICU program standards were core issues that affected the overall success of the tele-ICU programs. Compared with sites that showed respect, hub and rural spoke sites that did not show respect for each other's expertise had lower rates of use of tele-ICU, lower rates of site-to-site communication, and frequent misunderstandings in terms of the staff or site roles, goals, expectations, and protocols. Selected quotes from rural spoke site staff illustrate many of these issues (Table 3). Among the 3 hub-spoke networks studied, 1 had notably good relations between the hub site and the rural spoke sites. In this case, the hub site made substantial efforts to connect with and build relationships with the spoke sites.

Resistance by staff at the rural spoke sites was often interpreted as a lack of respect and appreciation of the expertise offered by the hub site. In these instances, hub sites reported that rural spoke sites responded with opposition and passive-aggressive behaviors when clinical guidance or reminders about protocols were provided. The clinical staff from the rural spoke sites reported feeling harshly or unduly criticized when feedback was provided by the hub staff and feeling that hub staff members were condescending. Rural clinical staff also felt that the hub site staff did not understand rural health issues and culture and did not know the patients, families, or social context of the illness as well as staff at the spoke site did (Table 3).

Forming a reciprocally supported staff training model that focuses on communication and cultural awareness may improve staff utilization and site-to-site relationships. For teamwork to occur, shared acknowledgment of each participating member's roles and responsibilities is important because adverse outcomes can arise from a series of seemingly trivial errors from ineffective teamwork. In this study, members of the rural spoke site thought that they were being watched and judged, but they were unaware that hub site nurses were monitoring about 40 patients at any given time. The hub site staff were often frustrated by having to explain to the spoke site providers that they are watching the patient, not evaluating the hub site staff (Table 3).

Spoke site physicians reported a need for increased peer-to-peer interactions between physicians rather than have hub site physicians or nurses
make clinical decisions and order the spoke site providers to carry out the actions with little or no communication or explanation. For example, a physician in a rural spoke site reported that she would appreciate a peer-to-peer relationship instead of the hub site submitting “orders” as if the spoke site was there to simply carry out instructions (Table 3). Rural spoke site physicians reported frequent miscommunications due to the hub site physician’s failure to understand the context of the rural site environment (eg, what medications and equipment were on hand). Hub site and rural spoke site staff largely agreed that establishing clear organizational and teamwork policies, including developing a system for sharing communication, cultural understanding, trust, and attitudes. For example, a hub physician was angry at the rural site for not following proper drip protocol, but we do not have one. The rural site ICU staff often float to other departments. The hub is often impatient because they do not understand the rural facility is operating with limited staff and resources.

| Table 3 |
| Sample quotes from field notes about problems between teams related to communication, cultural understanding, trust, and attitudes |

**Hub staff**

The rural site tele-ICU director tried to caution administration to be sensitive to medical staff needs and perceptions. The rural site doctors are “cowboys” who are set in their ways and do not appreciate interference. I suggested they take careful measures in setting groundwork and building trust, but this did not happen. Administration just came in with orders.

The rural site perceives themselves as the experts in providing care to rural patients. In order to achieve the level of benefit, the trust and communication details must be resolved.

The rural site often perceives the hub physicians as antagonistic. The interaction between doctors at the rural site and doctors at the hub was immediately strained and hostile. The rural site physicians stopped using tele-ICU in retaliation to the God-like orders and rude treatment from the hub.

The spoke team is not trusting of our tele-ICU nurses for the most part. They do not respect us. They do not know what kind of experience we have had and that we have all worked bedside in the ICU.

The general message from the rural physician to the hub in this case was keep your hands off my patient. This is a common perspective. Better communication and understanding of hub staff roles and background could help alleviate bad feelings and mistrust.

In one battle of wills between rural and hub site physicians, a septic patient needed to be transferred. The rural attending physician refused tele-ICU intervention. The patient’s infection and status became worse and he was finally transferred to another facility.

We have an annual open house for the hub site staff. The spoke site staff are invited to attend and see what we do. Usually not many of them attend.

Conflicts don’t happen often. As hub intensivists, we realize that we are not caring for the patient and we pick our battles. We need to let the little things go because we do not want to risk alienation.

I am here to help the rural sites. I want to know how I can help them provide the best patient care, but they do not understand me. I am not just a video box.

We invited rural hospitals to be a part of the grant to apply for money for the eICU. The sites had a choice and opted into the program. It was not forced on them.

[Name of hub site administrator] created a physician committee with spoke site doctors and uses this to parlay the doctors into a coalition to standardize practices. [Hub site clinical staff/administrators] also try to get invited to the remote site committee meetings.

**Spoke staff**

A couple of physicians who were early supporters of tele-ICU later felt disrespected by the hub physicians. Often the struggle between the physicians would put the nurses in the middle, which caused stress for the nurses and was not a good strategy for the patient.

It is important to see the rural staff and hub site staff as part of the same team. Relationship building can help with this.

The hub has to take care to be respectful and not challenge the bedside physician in a demeaning way but try to educate and explain.

A hub physician was angry at the rural site for not following proper drip protocol, but we do not have one. The rural site ICU staff often float to other departments. The hub is often impatient because they do not understand the rural facility is operating with limited staff and resources.

The hub staff are a huge help in recording everything during intense situations so the bedside nurse does not have to spend so much time documenting everything that happens during a critical incidence. The hub will view the patient room during a code and will provide friendly reminders to the bedside staff is something is overlooked. For example, some IVs initiated during a code are only run for specific amounts of time but if it is not discontinued, the hub will announce that it is still running so the bedside nurse can turn it off. During all the activity during a code, it is easy to lose track of all the details and it is helpful to have a second set of eyes and ears. The hub also records everything that happens during a code making bedside documentation much easier.

At first the nurses were against it. There was too much documentation and they did like someone telling us what to do. After we explained how an eICU works and [name of hub site administrator/nurse] came up here for a staff meeting—she has a dynamic personality—it was fine. Having [hub site administrator/nurse] meet the nurses created a connection that was very helpful.

Abbreviations: ICU, intensive care unit; IVs, intravenous catheters.
Providers on both the rural spoke and urban hub sites expressed the need for more clearly defined expectations.

Discussion

The objectives of this study were to use on-site interviews with clinicians and hospital administrators to identify organizational and teamwork factors associated with tele-ICU functionality, utilization, and effectiveness. We found that all participants considered tele-ICU important in quality patient care, but on both sides, clinicians did not see themselves as an integrated team. In all 3 of the hub sites and 7 of the 8 rural sites, the clinicians felt divided, having an “us versus them” mentality and thought that their respective “sides” were “misunderstood.” The cultural clashes left bedside nurses feeling as if they were in the “middle of a war” between the hub and spoke site physicians. The lack of clearly established roles and responsibilities and the ambiguity related to tele-ICU policies appeared to result in resistance of the spoke site staff to recommendations made by hub site staff.

The need for collaborative relationships between the hub and spoke teams was also apparent in other studies.6,17 In a study21 conducted with bedside nurses who use tele-ICU, 79% of the bedside nurses thought that personally knowing the telemedicine physician was important, and 61% stated that they were more likely to contact the tele-ICU if they knew the on-call physician. Although tele-ICU can improve clinical outcomes22,23 and improve the teamwork and safety climate,18 opportunities can also be missed because of misunderstandings21 and a lack of perceived usefulness or knowledge or both of the technologies among clinicians.24,25

As a result of our findings in the context of the previous reports,7,26 we developed suggestions for improvement that were based on the comments made by our study participants (Table 4). Rural spoke site clinicians reported feeling that the hub site staff did not understand the challenges of working in a rural hospital. The hub sites admitted having limited information on the rural population of patients and on the staffing issues, facilities, and working relationships that existed at the rural spoke hospital. For example, if a hub site ordered magnetic resonance imaging on Saturday morning and the imaging truck visited the spoke site on Tuesdays and Fridays only, then the usefulness of the images would likely be reduced because of the delay in obtaining them. A clear theme was that sharing information about the rural spoke site with the hub site would result in improved team relations and possibly improve patient outcomes.

We also found that hub and spoke sites that had guidelines and protocols established on how teams work together fared better than those that did not have guidelines. All networks had some guidelines to assist during times of conflict; however, few had established approaches to addressing conflicts, and many reported that these daily conflicts eventually led to resentment, bigger conflicts, and possibly adverse affects on patient care. The networks that lacked a process to provide feedback to share concerns between the teams had greater levels of frustration than did those that had a process. In order to stimulate oral dialogue, a designated person on each team could meet with the other team’s staff to communicate the concerns of the team of the designated person and listen to the concerns presented by the other team. The feedback mechanisms for problems, success stories, and positive interactions should also be shared. This point was also reported by Moeckli et al,6 who evaluated a tele-ICU program in the Veterans Affairs system among 7 hospitals, including 3 rural hospitals. The results indicated the importance of allotting time and resources for local coordination, continuous needs assessment for tele-ICU support, staff training, developing interpersonal relationships, and systems design and evaluation.

More than 1 million patients have received care through a tele-ICU system in the United States, and according to estimates, 11% of all ICU patients receiving care in nonfederal hospitals benefit from tele-ICU.27,28 Because of the critical issues that ICU patients experience, the high costs of providing care, the shortage of intensivists, and the high number of patients who receive care in tele-ICU programs, effective collaborative relationships must be developed to provide high-quality and cost-effective care, particularly for ICUs located in rural communities.29 The lessons learned in our study and our proposed recommendations could help existing tele-ICU programs and those under development and consideration. Our recommendations for existing programs and future policy changes and research are summarized in Table 4 and Table 5, respectively.

Our study has several limitations. Although we conducted interviews at 8 rural spoke sites
### Table 4
Solutions for improving outcomes for the tele–intensive care unit (tele-ICU)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misunderstandings and faulty assumptions about different sites (hub and spoke) leading to orders and requests for equipment and medications that are not available</td>
<td>Provide the hub site with facility information about the spoke sites. Provide role-reversal education. Hub site staff should have information about the spoke sites such as which imaging, laboratory tests, and medications readily available for staff to use.</td>
</tr>
<tr>
<td>Unrealistic expectations between hub and spokes about staff training, education, and abilities</td>
<td>Provide role-reversal education. Hub and rural sites may benefit from cross-site training and job shadowing. This step may help inform and define site roles and staff expectations/responsibilities in relation to the system or team as a whole. If spoke sites are unable to have staff visit the hub site, then providing an educational video about how the hub site works and incorporating it into their training is an alternative.</td>
</tr>
<tr>
<td>Poorly established relationships and communication with little trust or respect between hub and spoke staff</td>
<td>Strengthen relationships through team-building activities. Hub and rural site teams may benefit from cross-site team meetings before implementation as well as after. It may be cost prohibitive to have staff meet in person, but webinars or video conferencing may help facilitate regular team building. Another team building recommendation is to share information about the other team members, which may help personalize the interactions. The sharing could include a photo of the staff member with his or her background as well as some information about personal interests.</td>
</tr>
<tr>
<td>Little emphasis during staff orientation or staff development exercises focused on building relationships between health professionals</td>
<td>Identify and use program champions. The development of a tele-ICU program champion team among administrators, physicians, and nursing staff may help reduce initial resistance to use of the program. Program champions can promote the tele-ICU as a valuable learning and practice improvement tool.</td>
</tr>
<tr>
<td>Poorly defined leadership and communication so that problems arise that are not quickly addressed</td>
<td>Increase the availability of physician-to-physician consultations. Both hub and spoke clinicians tend to think they are providing the best relevant care possible. Rural physicians may reject hub site recommendations if a cooperative relationship has not been established. Hub and rural providers need to initiate peer-to-peer consultations and communication. When possible, hub sites should consult the attending physician before sending orders.</td>
</tr>
<tr>
<td>Conflict between hub and spoke physicians</td>
<td>Provide feedback mechanisms so that teams can share concerns, successes, and suggestions. Regularly collect data on satisfaction and collaboration from nurses, physicians, patients and patients’ families and administration at both sites. Follow-up could be through a designated point-person on each team to be the lead on sharing concerns and/or periodic evaluations. Staff meetings intended to share information (eg, success stories) would be valuable. Data also can be used to highlight successes.</td>
</tr>
</tbody>
</table>

### Table 5
Suggested program and policy changes and future research

Assess the effectiveness and impact of cross-training of hub and spoke site staff roles (eg, job sharing or hub and rural site staff role-reversal training). Assess the impact of staff from the tele–intensive care unit being strictly in the tele–intensive care unit or splitting their time between bedside care and at the hub or spoke site. Assess the effects of feedback and communication between staff at the hub and rural sites (eg, periodically evaluate the other team’s performance or have a neutral party from both the hub and spoke sites share the team’s concerns with the other team to facilitate communication in a nonthreatening or personal manner. Assess the impact of peer-to-peer physician consultations on a regular or as-needed basis. Involve the clinicians at hub and spoke sites to develop a team agreement.
participating in tele-ICU, our findings may not be representative of other rural tele-ICU spoke sites. One rural spoke site in our study withdrew from the study because of staffing, timing, and resource limitations, and this site may have had additional or different insights compared with the insights of spoke hubs that did participate. Another limitation was the small number of rural physicians included in the interviews. Although the study design included planned interviews with at least 1 administrator, 1 physician, and 1 nurse familiar with the tele-ICU at each rural spoke site, 3 physicians and 1 nurse at the rural spoke sites were unavailable because of patient care demands. Despite this situation, most likely this limitation had little effect on the study because of the relatively large number of interviews conducted and the emergence of core issues and themes. In addition, despite our inclusion of comments from individual participants, as in any qualitative research, we have no way of assessing whether the comments are generalizable to the universe of all tele-ICU staff. Last, because our semistructured interviews focused on how organizational and teamwork factors affect tele-ICU functionality, utilization, and effectiveness, we made the assumption that addressing these factors would improve tele-ICU outcomes. This assumption is not necessarily valid.

In order to realize the effectiveness of tele-ICUs, both hub and rural spoke site teams support the need for strong, collaborative relationships to promote organizational and teamwork factors. Our data indicate that role misunderstanding, lack of knowledge about the other team’s operations and positions, and territorial disputes can lead to lower staff satisfaction, missed educational opportunities, and suboptimal patient outcomes. Although a majority of hub and rural spoke site staff reported the beneficial effects of tele-ICUs, most also easily pointed to areas where improvements could be made. Our data also suggest that improvements in these factors can increase collaboration, utilization, and communication, all of which could lead to improved clinical outcomes. The beneficial effects may not be evident if only quantitative data are examined, but they are important because they improve staff capabilities, facility and standards of care outcomes, and the experiences of patients and their families. In addition, the complementary and combined skills and knowledge of dual teams need to be acknowledged and appreciated as being stronger than those of either the hub site or the spoke site alone and be embraced to meet patient and staff needs.

ACKNOWLEDGMENTS
Special thanks to Earl W. Ferguson, MD, PhD, Tessa Robinette, BS, and Mary Jo Ortiz, MA, for their contributions to this study from its conception to its completion. We also extend our gratitude to the participating study sites and their staff, whose commitment to providing accessible and quality health care in rural regions made this study possible.

FINANCIAL DISCLOSURES
WRMA, Inc conducted this study through funding from the Health Resources and Services Administration (HRSA) Federal Office of Rural Health Policy, contract number HHSH250200646016L. The findings do not represent the opinions of HRSA.

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SEE ALSO
For more about tele-ICUs, visit the Critical Care Nurse website, www.cnnonline.org, and read the article by Brindise et al, “Development of a Tele-ICU Postorientation Support Program for Bedside Nurses” (August 2015).

REFERENCES

To purchase electronic or print reprints, contact American Association of Critical-Care Nurses, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 899-1712 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
Background  Family-centered rounds involve purposeful interactions between patients’ families and care providers to refocus the delivery of care on patients’ needs.

Objectives  To examine perspectives of patients’ family members and health care providers on family participation in rounds in the surgical intensive care unit (ICU) and the potential use of telemedicine to facilitate this process.

Methods  Patients’ family members and surgical ICU care providers were recruited for semistructured interviews exploring stakeholders’ perspectives on family participation in ICU rounds and the potential role of telemedicine. Thirty-two interviews were conducted, audio recorded, and transcribed verbatim. Common coding methods were facilitated by using NVivo 10. A mean coding agreement of 97.3% was calculated for 22% of transcripts.

Results  Both patients’ family members and health care providers described inconsistent practices surrounding family participation in ICU rounds as well as barriers to and facilitators of family participation. Family members identified 3 primary logistical challenges to participation in ICU rounds: distance to hospitals, work/family obligations, and the rounding schedule. Both family members and providers reported receptivity to virtual participation as a potential solution to these challenges.

Conclusions  Understanding the barriers to and facilitators of family participation in ICU rounds is key to encouraging adoption of family-centered rounds. For families that live far away or have competing demands, telemedical options may facilitate participation. (American Journal of Critical Care. 2016;25:440-447)
In 2001, the Institute of Medicine issued a white paper calling for refocusing the delivery of health care on the needs and desires of patients. It was recommended that patients and their families be kept informed and actively involved in medical decision-making and management. Involvement of patients’ families in health care delivery is desirable in many settings, but perhaps nowhere more so than in the intensive care unit (ICU). Although the overall ability of ICU patients to make decisions for themselves is not well characterized, up to 95% of critically ill patients at the end of life are unable to make decisions for themselves, leaving family members to serve as proxies. In 2004, the American College of Critical Care Medicine drafted patient-centered intensive care practice guidelines that strongly encourage family presence and participation in the ICU.

Family-centered rounds (FCR) involve planned, purposeful interactions between patients’ families and the ICU team and is associated with improved family satisfaction scores for some elements of ICU care. Given the choice, 85% to 100% of families would prefer to be present during bedside rounds, yet this practice has not been universally adopted. Critical care rounding is a socially complex process involving patients, their family members, nurses, advanced practitioners, resident physicians, and attending physicians. Barriers to successful implementation can include provider resistance and the competing time commitments and financial constraints of family members.

One potential method to increase family participation in ICU rounds is use of telemedical platforms to allow virtual participation. In the past decade, the expansion of telemedicine into the ICU has increased coverage during off-hours and improved compliance with “best practices,” such as adherence to bundles for prevention of ventilator-associated pneumonia. However, less effort has focused on patient and family-centered endeavors. ICU care plans typically include a formal rounding period in the morning during which the events of the past 24 hours and plans for the upcoming day are discussed. Unfortunately, this provider-centric and relatively inflexible time frame may not allow patients’ family members who have competing time commitments to attend and may lead to degradation of communication between patients, their family members, and providers. The option of virtual participation by families has the potential to eliminate travel time to the ICU and reduce the time spent waiting for rounding teams.

As groundwork for a pilot project involving virtual participation of families in ICU rounds, we conducted a qualitative study to explore the perspectives of providers and patients’ family members on family participation in rounds and the potential role of telemedicine. These efforts may serve to inform future approaches to enhance clinical decision-making by patients, their families, and critical care providers.

Methods

Setting and Sample Selection

The research team interviewed providers and family members of patients who had been admitted to the ICU at the Hospital of the University of Pennsylvania, a large, urban teaching hospital. Family members were eligible to participate if they were at least 18 years of age, were the patient’s health...
care proxy, visited at least once, and the patient had an anticipated ICU stay of at least 72 hours. Purposive sampling identified ICU providers with a variety of clinical training and experience levels and included registered nurses, advanced practice nurses, resident physicians, and attending physicians. In current practice, family members are invited to participate in ICU care rounds by the primary nurse upon first contact with the patient's family and then daily thereafter if they are present at the bedside. At the time of this study, no telemedical platform to allow patients' family members to participate in rounds remotely was in place. Study participants were first interviewed regarding existing practices of family participation in ICU rounds, and then were asked to consider telemedical alternatives, operationalized as Skype (Microsoft Corp) or FaceTime (Apple Inc).

**Study Design**

This study consisted of 1-time, semistructured interviews. Parallel guides were developed for family member and provider interviews around 3 primary domains: (1) description of and participation in ICU rounds, (2) information sharing between patients' families and providers, and (3) perceptions of telemedicine. Additional probes were used to elicit further responses. This study was approved by our institutional review board.

**Data Collection and Analysis**

Interviews were conducted in-person or by phone by a trained qualitative interviewer and ranged from 11 to 45 minutes in length. Interviews were audio recorded, transcribed, and checked for accuracy against the original recording. Transcripts were then entered into NVivo 10 (QSR International Pty Ltd). Members of the research team independently coded the first 5 transcripts, employing open-coding strategies, and this initial set of codes was compared to create a codebook. This codebook was revised by using the constant comparative method to review coding both within and between transcripts. Double coding was used for 22% (7) of the transcripts to check codes applications, and intercoder reliability was calculated for double-coded transcripts. Codes with agreement less than 70% were resolved through consensus to reach a mean coding agreement of 97.3% (range, 87.1%-100%).

**Results**

**Characteristics of Sample**

We interviewed 32 family members and providers. Of family members, 20 of 23 (87%) agreed to participate (Table 1). The mean age of family participants was 53 years (range, 21-79 years). All 12 providers recruited agreed to participate (mean age, 36 years; range, 27-53 years). Providers were purposively recruited to garner a range of professional perspectives on family participation in ICU rounds (Table 2).

**ICU Rounds and Family Participation**

Comprehension of the structure of rounds differed substantially between the groups. Patients’ family members recalled how the structure, depth of discussion, and inclusion of family members

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. of participants</th>
</tr>
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<tbody>
<tr>
<td>Sex</td>
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<td>Biracial</td>
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<tr>
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<tr>
<td>Child</td>
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</tr>
<tr>
<td>Grandchild</td>
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<td>Parent</td>
<td>1</td>
</tr>
<tr>
<td>Cousin</td>
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<tr>
<td>Highest education level</td>
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<tr>
<td>High school or general equivalency diploma</td>
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</tr>
<tr>
<td>Some college or 2-year degree</td>
<td>8</td>
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<tr>
<td>4-year degree or graduate studies</td>
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<td>Annual income, $</td>
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<table>
<thead>
<tr>
<th>Characteristic</th>
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</thead>
<tbody>
<tr>
<td>Provider type</td>
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</tr>
<tr>
<td>Resident physician</td>
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<tr>
<td>Attending physician</td>
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<td>Race</td>
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<td>Black/African American</td>
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<tr>
<td>Asian</td>
<td>2</td>
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<tr>
<td>Years worked in hospital's intensive care unit</td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
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</tr>
<tr>
<td>1-5</td>
<td>6</td>
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<tr>
<td>6-10</td>
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<tr>
<td>&gt;10</td>
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</tr>
</tbody>
</table>

**Table 1**  
Characteristics of family member participants

**Table 2**  
Characteristics of providers
Both providers and family members described how telemedicine could make participation more convenient.
advantages (Table 6). Both providers and family members described how telemedicine could make participation more convenient by (1) eliminating travel to the hospital and (2) coordinating virtual participation with other commitments. Both provider and family members also explained how telemedicine could strengthen interpersonal communication between the ICU team and patients’ families. Interpersonal advantages of telemedicine included (1) development of more patient-centered care plans, (2) increased family understanding of the care plan, (3) display of nonverbal communication, and (4) providing a symbolic invitation for full engagement of patients’ families.

Both providers and family members also noted potential barriers to or drawbacks of telemedicine. The few family members who reported no interest in using telemedicine cited general discomfort and inexperience with technology as the primary reason. Providers appeared primarily concerned with the implementation of telemedicine in the ICU. One provider described how telemedicine might be
Family-centered rounding embraces a recognition of the patient and the patient’s family as the focus of care as well as of the importance of multidisciplinary cooperation, emotional support for the family, and clear and effective communication. Although family participation alone does not equate to family-centered rounds, family participation in rounds is a key permissive element for family-centered rounds to occur. Providers are generally supportive of family participation in ICU rounds, but levels of support may vary by discipline; 1 study showed that nurses were more supportive than physicians. In a recent study of pediatric ICUs, the prevalence of family participation on rounds was 44%.

This qualitative study is the first published study examining family participation in rounds in the general surgical ICU setting. A review of the recent literature revealed only 2 studies in the adult ICU population. Both care providers and patients’ family members described how initiation of family participation in rounds was often based on the tendencies of the rounding team, especially the attending physician. Family members described their confusion regarding the rounding structure and feared being perceived as “bothersome” or not understanding “medicalese.” Optimizing family participation in rounds therefore requires a balance between the best way for providers to communicate with one another and the best way for providers to communicate with patients’ families. Previous studies have reported providers’ perspectives on negative aspects of family participation in rounds, including decreased educational intensity and concerns about confidentiality. Although providers participating in this study did not appear to share these concerns, some felt that sharing “bad news” on rounds could be more difficult when families were present, consistent with other studies reporting concerns for decreased candor or comfort levels when discussing difficult topics with patients’ families present.

Both patients’ family members and health care providers in this study emphasized the logistical challenges to family participation in rounds. Physical presence at the bedside during rounds may be the most desired iteration of family presence, but widespread adoption of telemedical technology now makes virtual presence a feasible alternative when physical presence is not possible. Providers and family members in the study expressed how a virtual presence would not be a substitute for family member’s physical presence, but suggested it might

<table>
<thead>
<tr>
<th>Type of advantage</th>
<th>Specific advantage</th>
<th>Example quotations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convenience</td>
<td>No need for travel</td>
<td>If there was a way to really . . . [use telemedicine], that would be really positive because I don’t live here. So for somebody who has a loved one and you live out of state . . . that would be an excellent solution. [Family member] The distance that I have to travel—if I’m able to [use telemedicine], I can actually still be there and be able to get information that I needed. [Family member]</td>
</tr>
<tr>
<td>Fit in participation with other commitments</td>
<td>From the time I open my eyes to the time I close my eyes, I’m running. My schedule is completely busy . . . So this way [with telemedicine] you’re not missing out on work or inconveniencing your coworkers. [Family member] I don’t think they would have to be there every day, but at least some of the time it would be helpful to have their presence there. [Provider]</td>
<td></td>
</tr>
<tr>
<td>Interpersonal</td>
<td>Develop patient-centered care plans</td>
<td>We might provide better care and care that was more aligned with what the patient’s ultimate goals are if we could get them [family] to participate in [telemedicine] . . . The families, I think, help us reprioritize things. [Provider]</td>
</tr>
<tr>
<td></td>
<td>Understand care plans</td>
<td>It would be easier to be in on the conversation and see what’s going on with him and what their plans are for the day. [Family member]</td>
</tr>
<tr>
<td></td>
<td>Display nonverbal communication</td>
<td>Because a voice on the phone is different from a face and there’s a human body to that. [Provider]</td>
</tr>
<tr>
<td></td>
<td>Symbolic invitation for family participation</td>
<td>[Telemedicine] would show initiative on our part, showing the families that we want them to be part of it. Perception is half the battle. [Provider]</td>
</tr>
</tbody>
</table>

“cumbersome” to implement, noting demands for coordination on staff. Several providers conveyed a sense that telemedicine was a compromise between having the family present or not having the family participate at all. As one provider concluded, “It’s not being there. But it’s maybe better than missing it altogether.”

**Discussion**

Family-centered rounding embraces a recognition of the patient and the patient’s family as the focus of care. Several providers conveyed a sense that telemedicine was a compromise between having the family present or not having the family participate at all. Providers are generally supportive of family participation in ICU rounds, but levels of support may vary by discipline; 1 study showed that nurses were more supportive than physicians. In a recent study of pediatric ICUs, the prevalence of family participation on rounds was 44%.

This qualitative study is the first published study examining family participation in rounds in the general surgical ICU setting. A review of the recent literature revealed only 2 studies in the adult ICU population. Both care providers and patients’ family members described how initiation of family participation in rounds was often based on the tendencies of the rounding team, especially the attending physician. Family members described their confusion regarding the rounding structure and feared being perceived as “bothersome” or not understanding “medicalese.” Optimizing family participation in rounds therefore requires a balance between the best way for providers to communicate with one another and the best way for providers to communicate with patients’ families. Previous studies have reported providers’ perspectives on negative aspects of family participation in rounds, including decreased educational intensity and concerns about confidentiality. Although providers participating in this study did not appear to share these concerns, some felt that sharing “bad news” on rounds could be more difficult when families were present, consistent with other studies reporting concerns for decreased candor or comfort levels when discussing difficult topics with patients’ families present.

Both patients’ family members and health care providers in this study emphasized the logistical challenges to family participation in rounds. Physical presence at the bedside during rounds may be the most desired iteration of family presence, but widespread adoption of telemedical technology now makes virtual presence a feasible alternative when physical presence is not possible. Providers and family members in the study expressed how a virtual presence would not be a substitute for family member’s physical presence, but suggested it might
serve a supplemental role when physical presence was not possible. Although the ability to facilitate family-centered rounds is an important end in and of itself, use of telemedical platforms to allow virtual participation of patients’ families in ICU rounds could also contribute to other important outcomes. Virtual family participation is primarily a means to improve communication, and some evidence suggests that communication is the key to family satisfaction with ICU care.\textsuperscript{26–28} Moreover, virtual family participation could in some cases lead to earlier discussions about end-of-life care. In one recent study,\textsuperscript{29} clinicians reported that lack of both patients’ decision-making capacity and substitute decision makers were important barriers to discussions about the goals of care. Future research in this area should focus on whether or not telemedical platforms actually increase family participation in rounds, and if so, whether or not this increased participation translates into improved outcomes for patients.

Despite these theoretical benefits, both care providers and patients’ family members also voiced concerns with virtual presence. Family members most often cited unfamiliarity with audiovisual platforms as a potential barrier, whereas providers were largely concerned with technical aspects of implementation. The future of clinical practice of telemedicine for virtual family participation in rounds will be dependent on the availability of user-friendly and reliable platforms.

**Limitations**

This study had several limitations. First, the research team interviewed only those patients’ family members who were able to visit the hospital. Individuals who were not able to visit might have reported different challenges to participating and additionally might have increased interest in virtual participation. Second, family members’ satisfaction with communication with the critical care team may have been influenced by the health status and prognosis of the patient. Finally, the small numbers of specific provider types may limit thematic saturation with regard to provider-specific perspectives. Regardless of these limitations, these findings may be transferable to understanding participation of patients’ family members in the ICU in other similar settings.

**Conclusions**

Family participation in rounds is a critical component of patient-centered care. Although both the providers and family members in this study expressed a strong desire to include family members in rounds, both groups described inconsistency in initiation of family participation and identified communication and logistical challenges to family involvement. Both the health care providers and patients’ family members expressed receptivity to telemedical platforms that would allow the families to partake in rounds virtually should they not be physically present at the bedside.

**ACKNOWLEDGMENTS**

Dr Carr spends a portion of his time as director of the Emergency Care Coordination Center in the US Department of Health and Human Services. The views expressed here do not necessarily reflect those of the federal government.

**FINANCIAL DISCLOSURES**

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**REFERENCES**


To purchase electronic or print reprints, contact American Association of Critical-Care Nurses, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 899-1712 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
Background  Studies have shown an association between intensive care unit environments and symptoms of psychological distress in family members of critically ill patients.

Objective  To investigate levels of cardiac anxiety in family members of intensive care unit patients.

Methods  From March 2012 to July 2013, on the third day after the patient’s admission, 223 family members of 147 patients completed the Cardiac Anxiety Questionnaire. A total score was calculated from 3 subscales: fear and worry about heart sensations, avoidance of activities reproducing cardiac symptoms, and heart-focused attention and monitoring of cardiac activity.

Results  Among the family members, 142 were women (63.7%) and 81 (36.3%) were men, 150 (67.3%) were married, and 37 (16.6%) were unemployed. Their mean score for overall cardiac anxiety was 1.11 (SD, 0.64), significantly higher ($P$ < .001) than for the general Greek population. Although all 3 subscales scores were significantly higher than for the general population, the highest score was recorded for the avoidance subscale (mean, 1.77; SD, 0.68). The relationship to the patient had a significant effect on heart-focused attention ($F_5 = 3.51; P = .03$). The mean score for patients’ siblings (2.0; SD, 0.01) differed significantly ($P = .02$) from the mean for other family member groups. Older adults ($P = .02$) and married participants ($P = .05$) reported higher levels of fear and worry related to cardiac stimuli, and women further reported higher levels of cardioprotective avoidance behavior ($P = .02$).

Conclusions  A noticeable number of family members of critical care patients had moderate to severe cardiac anxiety during the hospitalization of their relatives. (American Journal of Critical Care. 2016;25:448-456)
The intensive care unit (ICU) is a stressful environment that may be associated with high anxiety levels among family members of ICU patients. This anxiety often has intense physical and psychological repercussions.1-4 In adapting themselves to the ICU environment, families must cope with major life-and-death issues such as end-of-life decisions, role alterations, grief concerns, financial matters, and family responsibilities.1,6 Moreover, they must confront emotional distress such as despair and fear, mainly because of the uncertainty about the progress of their loved one, the fear of death, and the unfamiliar or inhospitable environment of the ICU.2,6,7 Much of the emotional, mental, and social upheaval that patients’ family members experience is due to the inadequate amount of information the ICU staff members provide about patients’ clinical course and condition or, at least, to the lack of clarity.2,7

Consequently, researchers have become gradually interested in the emotional responses that family members of patients experience during the patients’ treatment in ICUs. Research into family experiences and their current needs during a patient’s hospitalization began in the 1970s.8 More recent studies9-13 have explored the role of the ICU environment in the development of anxiety, depression, and stress-related disorders as part of the general term “postintensive care syndrome–family.”9 For instance, in a study in 43 ICUs in France, Pochard et al9 found that 69% and 35% of the family members of patients treated in ICUs had symptoms of anxiety and depression, respectively. In another study,10 more than two-thirds of the family members who visited ICU patients had symptoms of anxiety or depression during the first few days of the patients’ hospitalization. Thus, levels of traumatic stress and posttraumatic stress disorder are high, with an estimation of risk ranging from 33% to 81%.11-14 Additionally, family members of ICU patients at high risk for mortality are at high risk for moderate to severe levels of traumatic stress, borderline anxiety, and depression.11

However, despite the efforts to establish the psychological distress of family members within the context of the ICU, the psychobiological distress of this experience has been ignored to a great degree.15 Because of the potential seriousness of the physical and psychological stress, a specific subtype of anxiety, heart-focused anxiety (HFA), might affect family members of critical care patients. HFA is defined as “a fear of cardiac-related events and sensations based on perceived harmful consequences.”16 Indicative symptoms of this type of anxiety are fear and worries about heart sensations and functioning (eg, palpitations, chest discomfort, and/or chest pain), avoidance of behaviors that might precipitate cardiac events (eg, physical exercising), and increased levels of heart-focused attention and monitoring of cardiac activity.16 Another important aspect of HFA is the existence of many medical conditions characterized by chest pain and psychological distress, including cardiac and noncardiac chest pain, illness phobias, and panic disorder.17-20 Moreover, HFA affects levels of general psychological distress by increasing sensitivity to anxiety and influences patient-reported physical health by increasing worry about heart-related symptoms.21

To our knowledge, little information on HFA (commonly referred to as cardiac anxiety) in family members of patients treated in ICUs is available. In this study, we aimed to identify the occurrence of the 3 distinct symptoms of HFA (fear, avoidance, attention) and the overall HFA in family members of patients admitted to ICUs and to compare the findings with data on the general population in Greece. We also explored the possible association of such symptoms with demographic characteristics (ie, age, sex, education, marital status, and type of relationship to the patient).
Methods

Setting
The study was conducted between March 2012 and July 2013 in the ICU of the University Hospital of Ioannina, Greece, and was approved by the ethics committee of the hospital. The ICU is a 14-bed unit for adults with medical and surgical conditions, and it admits approximately 450 to 500 patients per year. The staff consists of 12 physicians, 35 nurses, and 2 physiotherapists. The protocol for providing information to patients’ families includes 2 briefings daily. Visiting time is restricted to 30 minutes every afternoon, but many family members remain in the waiting room for a longer time.

All family members gave their consent before their inclusion in the study and completed the questionnaires in the waiting room of the ICU.

Participants and Procedure
Family members were defined as all relatives with any type of family bond and close friends who remained in the waiting room during a patient’s hospitalization. Only adults (>18 years old) with sufficient knowledge of the Greek language were invited to participate in this study, to be sure the participants understood the psychometric tools used. Exclusion criteria were any current medical diagnoses, cardiovascular diseases or use of cardiovascular medications, and any history of mental disorders requiring psychiatric medication. All interviews with a patient’s family members were carried out on the third day of the patient’s stay in the ICU. The participants were informed of the purpose of the study and were assured of the confidentiality and anonymity of the process.

Measurements and Evaluation of Symptoms of Cardiac Anxiety
A survey was used to collect sociodemographic information from the family members of the ICU patients (age, sex, date of birth, location of residence, education, employment, marital status, and relationship to the patient) and clinical characteristics such as medical records of cardiovascular disease and mental problems treated with medication. In addition, each participant completed the Greek version of the Cardiac Anxiety Questionnaire (CAQ).21 Age and sex were recorded for each patient.

The CAQ was used to assess subjective cardiac anxiety (ie, HFA).16 The Greek version of the CAQ consists of 10 items describing dimensions relevant to bodily perceptions of heart function.22 Each item was rated by using a 5-point Likert-type scale, with anchors of 0 (never) and 4 (always). The CAQ yields a total score and 3 subscale scores: fear and worry about thoracic and heart sensations, avoidance of activities thought to reproduce cardiac symptoms, and heart-focused attention and monitoring of cardiac activity.16,22 Both total and all subscale scores range from 0 to 4, and higher scores indicate higher levels of HFA.16,22 The Cronbach α for the Greek CAQ was considered satisfactory (α = 0.80), and the stability of the questionnaire was verified by a high test-retest reliability during a 3-month period (r = 0.86). The Greek CAQ provided evidence indicating the validity of the scale with respect to all aspects of the Symptom Checklist-90-Revised subscales.22

Statistical Analysis
All continuous data were screened for normality by using the Kolmogorov-Smirnov 1-sample test because the sample size was greater than 50. Percentages, mean values, and standard deviations are given in the tables and the text. The assumption of normality was retained for age (P = .28), CAQ fear (P = .10), CAQ avoidance (P = .11), CAQ attention (P = .14) and total CAQ score (P = .15), and therefore we used parametric tests in our analyses. The independent t test was used to compare the scores of men with the scores of women on the quantitative variables. In the next step, we compared the mean CAQ scores with scores reported for the general Greek population. The data derived from the adaptation and validation of the instrument in the Greek language and the procedure are described elsewhere.22 For comparison of means with the general population, STATA software (StataCorp) was used. One-way analysis of variance was used to test the effects of differences between subgroups of family relationships on HFA. For further investigation, we used multivariate analysis of variance and Pillai’s criterion to identify the possible association of symptoms of cardiac anxiety with each family member’s demographic characteristics. To regulate possible confounding, because group sizes were not equal, we used the type III sums of squares model.23 The statistics were analyzed by using SPSS, version 22.0 (IBM SPSS), and STATA software. A P value of .05 or less (2-tailed) was considered significant in all tests.

Results

Characteristics of Patients and Their Family Members
Of the 584 family members approached during a period of 16 months, 341 were eligible for the study and were invited to participate. A total of 241 of the eligible participants (70.7%) completed and...
returned the questionnaires (100 did not give their informed consent for inclusion in the study). In addition, 18 family members were excluded because they met some of the exclusion criteria or did not complete the questionnaires completely (10 participants were taking medications for cardiovascular problems, 3 were taking medication for anxiety disorders, and 5 did not fully complete the CAQ). The final sample consisted of 223 family members (81 men and 142 women) with a mean age 41.5 (SD, 1.9; range, 18-79) years representing 147 patients (mean age, 58.3 years; SD, 18.6 years). Age did not differ significantly between men and women ($t_{216} = 1.37; P = .17$). Of the critically ill patients, 103 were men (70.1%), and 44 were women (29.9%). Among participants, 1, 2, and 3 or more family members of a patient submitted questionnaire replies for a total of 90, 42, and 15 patients, respectively. Of the family members, 150 (67.3%) were married, 70 (31.4%) resided in a city with more than 150,000 inhabitants, 79 (35.4%) cohabited with the patient, 94 (42.2%) had a university degree, and 37 (16.6%) were unemployed. Differences in sociodemographic data were not significant except for occupational status between men and women ($P < .001$). Relationships to the patient were as follows: 91 grown children (40.8%), 43 siblings (19.3%), 36 spouses (16.1%), 11 parents (4.9%), 38 other family members (17.0%), and 4 friends (1.8%). The percentages in terms of type of family relationship by sex and the whole sample are shown in Figure 1.

**Cardiac Anxiety Symptoms of Family Members**

The mean overall score for cardiac anxiety for the family members was 1.11 (SD, 0.64; range, 0-3.5). For the 3 distinct cardiac anxiety symptoms, mean scores were 1.13 (SD, 0.89; range, 0-4) for fear, 1.77 (SD, 0.68; range, 1-3) for avoidance, and 1.50 (SD, 0.90; range, 1-3) for attention. Men and women did not differ significantly for levels of fear ($t_{221} = 1.61; P = .12$), attention ($t_{221} = 1.13; P = .25$), and total score of cardiac anxiety ($t_{221} = 1.01; P = .32$). However, levels of avoidance were significantly higher ($t_{221} = 2.30; P = .02$) for women (mean, 1.84; SD, 0.69) than for men (mean, 1.62; SD, 0.63). For all 4 variables, scores were significantly higher for family members of critically ill patients than for the general Greek population ($P < .001$; Table 1).

For comparison of clinical results with the severity of the symptoms of cardiac anxiety, participants were divided into 4 subcategories according to the range of the total and all subscale CAQ scores. The 4 subcategories of risk for HFA were low (range, 0 to <1), moderate (range, 1 to <2), high (range, 2 to <3), and severe (range, 3-4). The distribution in the different subcategories of CAQ indicated that, in total, 21% of the family members had high to severe risk for fear and worry related to heart function, 61% had high to severe risk for cardioprotective avoidance behavior, 49% had high to severe risk for heart-focused attention and monitoring of cardiac activity, and 12% had high to severe risk for total cardiac anxiety (Figure 2).

**Comparisons Among Family Members**

A 1-way analysis of variance was conducted to compare the effect of types of family relationship within the dimensions of HFA. The results of the

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**Table 1**

<table>
<thead>
<tr>
<th>CAQ variable</th>
<th>Family members of ICU patients (n = 223)</th>
<th>General Greek population (n = 598)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Score, mean (SD), range</td>
<td></td>
</tr>
<tr>
<td>Fear</td>
<td>1.13 (0.89), 0-4</td>
<td>0.88 (0.86), 0-4</td>
</tr>
<tr>
<td>Avoidance</td>
<td>1.77 (0.68), 1-3</td>
<td>1.01 (0.91), 0-4</td>
</tr>
<tr>
<td>Attention</td>
<td>1.50 (0.90), 1-3</td>
<td>0.69 (0.64), 0-4</td>
</tr>
<tr>
<td>Total CAQ score</td>
<td>1.11 (0.64), 0-3.5</td>
<td>0.90 (0.60), 0-4</td>
</tr>
</tbody>
</table>

Abbreviation: ICU, intensive care unit.

* Use of the t test immediate command in Stata yielded a significant difference ($P < .001$) in scores between family members and the general Greek population for all 4 variables.
Levene test for homogeneity of variance were not significant on all CAQ variables (CAQ fear: $P = .29$; CAQ avoidance: $P = .13$; CAQ attention: $P = .18$; and total CAQ score: $P = .22$). A main effect was found for the relationship to the patient with the heart-focused attention: $F_5 = 3.51; P = .03$. Post hoc comparisons with the Bonferroni test indicated that the mean score for the patients’ siblings (mean, 2.0; SD, 0.01; range, 1.5-3.5) differed significantly ($P = .02$) from the mean score for patients’ children (mean, 1.74; SD, 0.68; range, 1-3). However, scores for attention of patients’ spouses (mean, 1.84; SD, 0.63; range, 1-2.7), parents (mean, 1.92; SD, 0.50; range, 1-2.3), friends (mean, 1.61; SD, 0.68; range, 1-3), and other family members (mean, 1.64; SD, 0.68; range, 1-3) did not differ significantly from those of patients’ siblings and patients’ children. No significant associations were detected between type of family relationship and fear ($F_5 = 1.88; P = .09$), avoidance ($F_5 = 1.14; P = .34$), and total HFA ($F_5 = 1.91; P = .09$; Table 2).

**Associations Between Symptoms of Cardiac Anxiety and Demographic Variables**

A multivariate analysis of variance was conducted with 4 demographic variables as independent variables and the 3 distinct symptoms of HFA (ie, fear, avoidance, attention) as dependent variables. Total CAQ score were not included in this model because the correlation coefficient for this variable was greater than the accepted limit ($r = 0.74$).24 The independent variables were age group (ie, young adults, adults, and older adults), marital status, and education level of the ICU patients’ family members, and only the significant results are reported. The multivariate result was significant for sex (Pillai trace = .05; $F_{5,92} = 3.93; P = .04$), age (Pillai trace = .05, $F_{6,72} = 2.99; P = .02$), and marital status (Pillai trace = .05; $F_{5,61} = 3.46; P = .03$). The criterion of homogeneity was not violated for the 3 dimensions of CAQ ($P = .44$). The univariate $F$ tests revealed a significant difference between men and women for avoidance scores, $F_{1} = 5.30; P = .02$, indicating that women reported higher levels of the cardioprotective avoidance behavior than men did. Furthermore, univariate significant differences were found for age ($F_{2} = 3.17; P = .05$), indicating a difference among age groups in the level of fear and worry about thoracic and heart sensations. Multiple comparisons with the Bonferroni criterion indicated that older adults reported significantly higher levels of fear than did adults and younger adults ($P = .02$) The univariate $F$ tests, in addition, showed a considerable difference for marital status ($F_{2} = 3.07; P = .05$), proving that married family members of ICU patients had significantly higher levels ($P = .05$) of fear than did single and divorced family members. The results of

**Figure 2** Distribution of the severity of symptoms according to score on the Cardiac Anxiety Questionnaire (CAQ) in family members of patients in the intensive care unit.

![Figure 2](image-url)
the multivariate analysis of variance are described in Table 3, and the profile plots of the estimated marginal means are shown in Figure 3.

**Discussion**

We evaluated the symptoms of cardiac anxiety (i.e., HFA) in 223 Greek family members of critically ill patients, and we concluded that high numbers of family members of ICU patients experience high levels of this particular type of anxiety. Furthermore, compared with the general Greek population, family members had statistically higher scores for the 3 distinct symptoms of cardiac anxiety and in overall anxiety levels as measured by the Greek version of the CAQ.

To our knowledge, this study is the first on cardiac anxiety in family members of ICU patients. In our initial screening, we found that 1 of 5 family members had high risk for fear and worry about heart stimuli and function, 2 of 5 had high risk for avoidance behavior to diminish cardiac-related symptoms, and 1 of 2 had high risk for heart-focused attention and monitoring of cardiac function. Moreover, the avoidance subscale had the highest mean value of all subscales used in the study. Of note, family members of critically ill patients experienced cardiac anxiety during the first 3 days of the patient’s hospitalization, and this anxiety should be taken into account by ICU doctors and nurses.1-15

To some extent, our results support previous findings9-11 that family members of ICU patients experience acute stress, anxiety, depression, and stress-related disorders. Indeed, having a loved one close to death is a great burden and increases the psychological symptoms among the family members of patients in critical care units.5-15 These psychological symptoms are explained in terms of severity of the patient’s illness and the family members’ fear of the patient’s death.10 However, our findings provide additional information on the biopsychological reactions among families of ICU patients. Severe symptoms of cardiac anxiety after adaptation to the ICU environment may indicate that a patient’s family members additionally confront their own health

**Table 3**
Multivariate analysis of variance (MANOVA) testing of Cardiac Anxiety Questionnaire (CAQ) scores according to different groups of demographic characteristics of family members

<table>
<thead>
<tr>
<th>Demographic characteristic</th>
<th>CAQ variablea</th>
<th>MANOVA test Pillai trace = .05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men (n=81)</td>
<td>1.14 (0.87)</td>
<td>1.62 (0.63)</td>
</tr>
<tr>
<td>Women (n=142)</td>
<td>1.12 (0.90)</td>
<td>1.84 (0.90)</td>
</tr>
<tr>
<td>F</td>
<td>0.26</td>
<td>5.30 (P=.02)</td>
</tr>
<tr>
<td>Comparisonb</td>
<td>1 &gt; 0 (P=.02)</td>
<td></td>
</tr>
<tr>
<td>Age group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Young adults (18-34 years old)</td>
<td>0.99 (0.81)</td>
<td>1.64 (0.68)</td>
</tr>
<tr>
<td>Adults (35-64 years old)</td>
<td>1.24 (0.91)</td>
<td>1.74 (0.67)</td>
</tr>
<tr>
<td>Older adults (≥65 years old)</td>
<td>1.83 (0.44)</td>
<td>1.84 (0.73)</td>
</tr>
<tr>
<td>F</td>
<td>3.17 (P=.05)</td>
<td>1.13</td>
</tr>
<tr>
<td>Post hoc comparisonc</td>
<td>2 &gt; 0 and 1 (P=.02)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary (n=22)</td>
<td>1.23 (0.94)</td>
<td>1.75 (0.69)</td>
</tr>
<tr>
<td>Secondary (3 years, n=22)</td>
<td>1.15 (0.87)</td>
<td>1.93 (0.60)</td>
</tr>
<tr>
<td>Secondary (6 years, n=85)</td>
<td>1.22 (0.89)</td>
<td>1.08 (0.66)</td>
</tr>
<tr>
<td>Higher education (graduate, n=71)</td>
<td>1.05 (0.87)</td>
<td>1.77 (0.67)</td>
</tr>
<tr>
<td>Postgraduate (n=23)</td>
<td>0.09 (0.95)</td>
<td>1.42 (0.68)</td>
</tr>
<tr>
<td>F</td>
<td>0.77</td>
<td>1.95</td>
</tr>
<tr>
<td>Post hoc comparisond</td>
<td>1 &gt; 0 and 2 (P=.05)</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single (n=64)</td>
<td>0.91 (0.85)</td>
<td>1.47 (0.54)</td>
</tr>
<tr>
<td>Married/spouse (n=150)</td>
<td>1.02 (0.91)</td>
<td>1.51 (0.54)</td>
</tr>
<tr>
<td>Divorced (n=9)</td>
<td>0.09 (0.51)</td>
<td>1.55 (0.52)</td>
</tr>
<tr>
<td>F</td>
<td>3.07 (P=.05)</td>
<td>0.38</td>
</tr>
<tr>
<td>Post hoc comparisone</td>
<td>1 &gt; 0 and 2 (P=.05)</td>
<td></td>
</tr>
</tbody>
</table>

a For each demographic characteristic, CAQ score is listed as mean (SD).
b 0 = Men, 1 = women.
c 0 = Young adults, 1 = adults, 2 = older adults.
d Not applicable.
e 0 = Single, 1 = married/spouse, 2 = divorced.
concerns related to cardiac function. Thus, our results suggest that the ICU adaptation is triggering a mind-body hypervigilance in family members and an increased tendency to become upset and worried about heart-related symptoms such as palpitations, chest discomfort, and/or chest pain. Such bodily discomfort typically meets criteria for a limited-symptom panic attack, whereas heart-related interpretation of a false alarm is significant in higher levels of HFA. Moreover, higher avoidance scores are strongly related to poorer physical health. However, we did not determine if the causes of these symptoms are due to the patient’s critical condition or to the ICU environment itself.

A novel finding in our study was the increased impact of heart-focused attention and monitoring for symptoms of cardiac dysfunction among siblings of ICU patients. This finding is intriguing because the focus of existing data is the elevated levels of psychological distress among patients’ spouses. A possible explanation for this apparent discrepancy is that we evaluated a specific type of anxiety, whereas other investigators examined the more general postintensive care syndrome–family in terms of depression and anxiety. From another psychological perspective, perhaps a patient’s siblings identify themselves (ie, similarities of self-concept, emotional reactivity, personality, intellect, sociability, beliefs, and attitudes) more with the patient than do the rest of the patients’ relatives and friends and therefore may perceive the ICU admission as an alert for the siblings’ own health. However, the observed difference was small and thus should be considered with caution. We also
found that older adults and married participants reported higher levels of fear and worry related to cardiac stimuli and that women further reported higher levels of cardioprotective avoidance behavior. These results are in accordance with previous findings\(^{10,12,26}\) on different psychological responses associated with age, sex, and marital status in ICU patients’ family members. Taken together, these findings suggest that implementing a support system with a focus on cognitive behavioral approaches for family members of ICU patients might improve the family members’ symptoms of cardiac anxiety as well as their general physical and psychological health.

**Strengths and Limitations**

Our study was a first attempt to measure HFA in a large sample of ICU patients’ family members, and the number of participants in the study is a major strength of the research. One limitation of our study is that we did not evaluate family members’ cardiac anxiety in relation to general anxiety and depression after patients’ discharge from the ICU; therefore, correlating these symptoms with either the patients’ stay in the ICU or with the visiting hours in the ICU was not feasible. Another limitation is that we used a self-report tool to measure cardiac anxiety. Although the tool is valid, respondents’ recall biases might have affected the results.

**Conclusions**

Hospitalization of a patient in an ICU is a factor with psychological implications for the patient’s family members. Our results highlight the risk for symptoms of cardiac anxiety among patients’ family members and emphasize the need for examination of this factor by the ICU staff. However future research is needed to confirm our results. Targeting a psychological supportive system for the family members of ICU patients may diminish the possibility of cardiac anxiety symptoms.

**ACKNOWLEDGMENTS**

This research was performed at the University of Ioannina, Medical School, Division of Internal Medicine, Department of Intensive Care. We thank the health professionals of the ICU for their contribution to this study.

**FINANCIAL DISCLOSURES**

None reported.

**eLetters**

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The New Sepsis Definitions: Implications for Critical Care Practitioners

By Ruth M. Kleinpell, RN, PhD, Christa A. Schorr, RN, MSN, NEA-BC, and Robert A. Balk, MD

Sepsis and septic shock are common, pathophysiologically complex, clinical conditions that are associated with high morbidity, mortality, and cost of care. Sepsis occurs in response to infection and results in sepsis-related organ system dysfunction and/or circulatory shock, which have high morbidity and mortality rates for hospitalized patients. Although estimates show trends toward decreases in hospital and case fatality rates, the incidence of sepsis cases is increasing. These developments have resulted in a large number of sepsis-related fatalities and a larger number of survivors who require posthospital care and/or are unable to resume their prior occupation.

Although a growing number of potential biomarkers have been studied to improve the capability of diagnosing sepsis, most lack specificity. Clinicians are currently using clinical criteria for sepsis surveillance and identification that are based on prior consensus definitions. These definitions, however, have limitations. Recently, a third sepsis definitions conference published new definitions and clinical criteria for the diagnosis of sepsis and septic shock. This article reviews highlights of the new sepsis definitions, including implications for practicing critical care clinicians.

Sepsis Definitions

Before 1980, sepsis was predominantly defined by bacteremia and shock. In the 1980s, clinical criteria were used to diagnose sepsis and septic shock. Researchers noted that approximately one-third of participants included in clinical trials had bacteremia and about one-third of participants had no identifiable source or site of infection. This situation led to the concept of the “sepsis syndrome.” In the late 1980s and 1990s, a number of potential early treatment strategies were available, such as antibodies against endotoxin, interleukin 1, tumor necrosis factor, and interleukin 10, all of which required early identification of potential cases of sepsis in an attempt to disrupt the inflammatory process and improve the outcome for patients with clinical sepsis. The Society of Critical Care Medicine and the American College of Chest Physicians convened a consensus conference in Chicago in 1991 with a primary goal of defining sepsis by using readily and rapidly available clinical criteria and enhancing communication on the topic of sepsis, severe sepsis, and septic shock in medical publications. At the conference, it also was noted that the presence of multiple organ dysfunction syndrome was associated with an increased potential for morbidity and mortality. At that time, sepsis was recognized as an important clinical entity although the pathophysiologic processes involved were poorly understood. Early treatment efforts suggested that interrupting the systemic proinflammatory pathways that led to sepsis was a strategy to decrease mortality and morbidity in critically ill infected patients. It was soon realized that sepsis pathophysiology was much more complex than just an overzealous proinflammatory response and that an anti-inflammatory response occurs along with activation of the immune system, coagulation system, and complement system in an attempt to mitigate the infectious process.

The goal of the first international sepsis definitions consensus conference was to identify a set of clinical parameters to aid in the early recognition of sepsis to assist in enrolling patients in clinical trials investigating innovative sepsis therapies designed to block the proinflammatory pathway. In addition, the definitions would aid in medical communication, eliminating confusion concerning the clinical syndrome, and thus allow outcomes to be compared over time and with different interventions. Definitions of sepsis and the systemic inflammatory response...
Definitions of sepsis and the systemic inflammatory response syndrome were proposed. Specific definitions for severe sepsis, septic shock, and hypotension, and the concept of multiple organ dysfunction syndrome (MODS) also were outlined. Although a number of clinical findings seen in patients with sepsis such as fever, tachypnea, tachycardia, hypotension, changes in mental status, leukocytosis, thrombocytopenia, and coagulation abnormalities were considered for inclusion in the definition of sepsis, a subset of manifestations that were easily identifiable was selected. These manifestations included changes in body temperature, heart rate, respiratory rate (and the need for mechanical support as a result of sepsis), and white blood cell count (elevated, lowered, or an increase in neutrophils [bands]), which were used to designate the systemic inflammatory response syndrome (SIRS). The limitations of the SIRS criteria were acknowledged, but the criteria provided a useful clinical tool for identifying patients with sepsis when 2 of the 4 criteria were present.

The consensus conference participants identified that a key component of the definition of sepsis was to identify dysregulated alterations in perfusion or organ dysfunction that occurred as a result of the systemic manifestation of infection. The term septic shock was used to define a state of hemodynamic alterations and/or acidosis, sepsis with organ dysfunction was defined as severe sepsis, and the resulting progressive sepsis-related organ dysfunction was defined as multiple organ dysfunction syndrome (MODS).

The Second International Sepsis Definitions

The second international sepsis definition conference was held in 2001 to further enhance the specificity of the original 1991 definition. The final report of the 2001 sepsis definitions conference recognized that the current concepts of sepsis, severe sepsis, and septic shock remained useful to clinicians and researchers, but also acknowledged that the diagnostic criteria for SIRS were overly sensitive and nonspecific. An expanded list of signs and symptoms to acknowledge predisposing conditions, the nature and extent of the insult and the magnitude of the host response, and the degree of resulting organ dysfunction was proposed as a staging system to better reflect the clinical response to infection and to aid in communication about sepsis in a fashion similar to how the TNM system for classification of malignant tumors aids in communication about malignant neoplasms. The expanded list of diagnostic criteria assisted clinicians in identifying patients with possible sepsis, and PIRO was a hypothetical model for staging and communicating about sepsis. Despite the expansion of the characterization of predisposing factors, premorbid conditions, the nature of underlying infection, the characteristics of the host response, and the extent of the resultant organ dysfunction, the need for better recognition of sepsis remained.

The use of the SIRS criteria to identify sepsis has been controversial since the initial proposal; the criteria have been criticized as being overly sensitive and not clinically useful because SIRS criteria can be present in a great many hospitalized patients, including patients in whom infection never develops, SIRS criteria in patients in the intensive care unit (ICU) correlated with mortality in a study of critically ill patients, but other reports noted that a significant proportion of patients with sepsis do not manifest SIRS criteria. In a recent study of 1,171,797 patients from 172 ICUs in Australia and New Zealand over a 14-year timeline, researchers reported that among 109,663 patients with infection and organ failure, 13.278 (12.1%) did not have SIRS criteria indicative of sepsis. The results indicate that 1 in 8 patients admitted with severe sepsis had significant morbidity and mortality, despite not meeting the SIRS criteria for the definition of sepsis. A recent study of the incidence and prognostic value...
Sepsis is now defined as a life-threatening organ dysfunction resulting from a dysregulated host response to infection.

Table 1
Evolving definitions of sepsis

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Infection</td>
<td>Pathological process caused by invasion of normally sterile tissue, or fluid or body cavity by pathogenic or potentially pathogenic microorganisms</td>
<td>Unchanged; New: PIRO system for staging sepsis (Predisposition; Insult [Infection], Response, Organ dysfunction)</td>
<td>Not defined</td>
</tr>
<tr>
<td>Sepsis</td>
<td>Clinical response arising from infection Systemic inflammatory response syndrome (SIRS) proposed to define the inflammatory process, independent of its cause</td>
<td>SIRS + suspected infection</td>
<td>Life-threatening organ dysfunction caused by a dysregulated host response to infection SIRS removed from definitions</td>
</tr>
<tr>
<td>Severe sepsis</td>
<td>Sepsis associated with organ dysfunction The term MODS was proposed (multiple organ dysfunction syndrome = presence of altered organ function in an acutely ill patient such that homeostasis cannot be maintained without intervention)</td>
<td>Sepsis + any of the following: Systolic blood pressure &lt; 90 mm Hg or mean arterial pressure (MAP) &lt; 60 mm Hg; lactate &gt; 2 mmol/L; international normalized ratio (INR) &gt; 1.5 or partial thromboplastin time (PTT) &gt; 60 s; creatinine &gt; 2.1 mg/dL; urine output &lt; 0.5 mL/kg per hour (≥ 2 h); platelets 100 x 10^9/L; SpO₂ &lt; 90% (room air)</td>
<td>Removed from definitions</td>
</tr>
<tr>
<td>Septic shock</td>
<td>Sepsis-induced with hypotension despite adequate fluid resuscitation along with presence of perfusion abnormalities that may include but are not limited to lactic acidosis, oliguria, or an acute alteration in mental status</td>
<td>Sepsis + hypotension despite adequate fluid resuscitation</td>
<td>A subset of sepsis in which circulatory, cellular, and metabolic alterations are associated with a higher mortality rate than sepsis alone</td>
</tr>
</tbody>
</table>

of SIRS and organ dysfunctions in 269,951 hospitalized patients from 5 hospitals also highlighted the difficulty with using SIRS, as 47% of patients (n = 125,841) met 2 or more SIRS criteria at least once during their hospital stay despite not being critically ill or having sepsis.26

The Third International Sepsis Definitions

The Third International Consensus Definitions Task Force (Sepsis-3) recently revised the definitions. Sepsis is now defined as a life-threatening organ dysfunction resulting from a dysregulated host response to infection.11 Septic shock is defined as a subset of sepsis in which circulatory, cellular, and metabolic alterations are associated with a higher mortality rate than sepsis alone.11 The third consensus definition task force recommended elimination of the terms sepsis syndrome, septicemia, and severe sepsis. Criteria for identifying organ dysfunction were outlined. These revolved around the Sepsis-related (Sequential) Organ Failure Assessment (SOFA) score, as this is a long-established score with good predictive validity and, importantly, it uses routinely measured variables, namely, ratio of \( \text{PaO}_2 \) to fraction of inspired oxygen (\( \text{FiO}_2 \)), score on the Glasgow Coma Scale, mean arterial pressure, serum level of creatinine or urine output, bilirubin level, platelet count, and type, dose, and rate of vasopressor/inotrope therapy.27 Organ dysfunction is identified by an increase in the SOFA score of 2 points or more as a direct result of the infectious process. However, the task force did acknowledge the limitations of the SOFA score: it does not accurately reflect current use of vasopressors and it can be influenced to some degree by clinician management. Table 1 outlines the evolving
definitions of sepsis from the original first consensus conference to the third consensus conference.

Third International Consensus Definitions Process

The process for revising the definitions of sepsis and septic shock and providing clinical criteria to aid clinicians in identifying patients who may have sepsis was a 2-year-long process that involved several components. The clinical criteria for sepsis were formulated by using a data-driven approach to identify clinical and laboratory characteristics that identified patients with suspected infection who went on to have poor outcomes. The discovery dataset comprised 1.3 million electronic health record encounters from January 1, 2010, to December 31, 2012, at 12 hospitals in southwestern Pennsylvania within the University of Pittsburgh Medical Center system (UPMC). A random split sample was used to develop new criteria to identify at-risk infected patients and to then compare these new criteria against existing severity scores, namely, the SOFA score, SIRS criteria, and the Logistic Organ Dysfunction System (LODS) score. The new model, named the quick SOFA (qSOFA) score, consisted of 3 clinical parameters: systolic hypotension (≤ 100 mm Hg), tachypnea (≥ 22 breaths per minute), and GCS score of 13 or less. Reanalysis showed that a GCS score of 14 or less was virtually as predictive as a GCS of 13 or less, so for practical and pragmatic reasons, any new alteration in mentation was adopted for qSOFA. One point could be awarded for each of the 3 criteria fulfilled, thus the qSOFA score would range from 0 to 3 points. Comparisons were made with respect to predictive validity for in-hospital mortality. For ICU encounters (n = 7932 with suspected infection, of whom 1289 [16%] died), the predictive validity for in-hospital mortality was lower for SIRS and qSOFA than for SOFA or LODS. For non-ICU encounters in the validation cohort (n = 66 522 with suspected infection, of whom 1886 [3%] died), qSOFA had predictive validity that was greater than SOFA and SIRS. Encounters with qSOFA scores of 2 or higher had a 3- to 14-fold increase in hospital mortality compared with qSOFA scores lower than 2.

The predictive validity for in-hospital mortality of SOFA among ICU encounters was not significantly different than that for the more complex LODS but was significantly greater than the predictive validity of SIRS and qSOFA, supporting use of SOFA in clinical criteria for sepsis. The predictive validity for in-hospital mortality of qSOFA among encounters with suspected infection outside the ICU was significantly greater than the predictive validity of SOFA and SIRS, supporting use of qSOFA as a clinical prompt to consider possible sepsis.

These risk assessment scores were then validated by using datasets comprising a further 3.5 million patients from the Kaiser Permanente group in Northern California (KPNC), a 130-hospital Veterans Administration health system database, an emergency medical services database (King County Seattle), and a database from an infection control study in Germany focusing on reducing the rate of health care–associated infections and related sepsis (ALERTS).

The clinical criteria for septic shock were formulated and validated by using multiple methods. A systematic review and meta-analysis of criteria used in observational studies reporting sepsis epidemiology of adult patients published between January 1992 and December 2015 identified 44 studies reporting septic shock outcomes (total of 166,479 patients) from 92 sepsis epidemiology studies. Overall, the crude mortality rate associated with septic shock was 46.5%, but there was a 4-fold variation in mortality and a 10-fold variation in incidence between studies, depending on the criteria used to define shock.

A Delphi study among the 19-member task force with 3 surveys and discussion of results from the systematic review was used to achieve consensus on the new definitions. The task force considered that septic shock should be defined as “a subset of sepsis in which particularly profound circulatory, cellular and metabolic abnormalities are associated with a greater risk of mortality than with sepsis alone.” The Delphi process identified hypotension and vasopressor therapy (representing cardiovascular dysfunction), and serum lactate level (representing cellular and metabolic abnormalities) as variables to test as clinical criteria by using cohort studies, as these parameters are routinely collected in most severely ill patients with sepsis.

The Surviving Sepsis Campaign (SSC) registry, with its more than 28,000 patients, along with the UPMC and KPNC data sets, was used to derive and validate clinical criteria to describe septic shock. The SSC database review demonstrated that fluid-resuscitated patients requiring vasopressors to maintain a mean arterial pressure (MAP) of 65 mm Hg or greater in addition to a serum lactate level of 2 mmol/L (18 mg/dL) or higher had significantly higher mortality (42.3% [95% CI, 41.2%-43.3%]) than did patients meeting any 1 or any combination of 2 of these parameters. These findings were then validated in the UPMC and KPNC data sets.

SOFa and qSOFa

Recognizing the limitation of being able to obtain the necessary data to calculate a SOFA score quickly in settings outside of the ICU, the new bedside clinical score termed qSOFA was delineated to help identify those patients who are likely to have a
prolonged ICU stay or are at increased risk of hospital death. Importantly, until further prospective data are collected to validate qSOFA in different healthcare settings, qSOFA should not be used as a diagnostic tool for sepsis but rather as a risk stratification tool. Use of qSOFA screening is recommended to prompt clinicians to assess for organ dysfunction, escalate therapy, refer to critical care, or increase monitoring if those processes are not already underway.11

The criteria to describe septic shock in Sepsis-3 do differ from the criteria currently used by the SSC that describes septic shock as “severe sepsis plus hypotension not reversed with fluid resuscitation.” Analysis of the SSC database reveals mortality rates of 42.3% when the Sepsis-3 criteria are used, 30.1% for hypotension with a lactate level of 2 mmol/L or less, and 25.7% for patients with a lactate level of 2 mmol/L or greater but with no hypotension. Of note, mortality in patients with severe sepsis but without either hyperlactatemia or vasopressor-dependent hypotension was 25.0% (Mervyn Singer, MD, personal communication, July 22, 2016).

**Implications for Clinical Practice**

The new sepsis definitions have direct implications for clinical practice, as use of the clinical criteria can promote identification of patients with sepsis and septic shock. It is well established that early clinical recognition of sepsis and prompt treatment can improve outcomes for patients, including decreasing mortality rates.2 Promoting awareness of the new definitions of sepsis and septic shock is a current clinical priority to ensure that critical care clinicians have knowledge of the updated definitions and the recommended use of the clinical criteria.

Although prospective validation in multiple US and non-US settings was recommended by the authors, the new definitions and scoring tools may currently be incorporated into some clinical practice settings. The new definitions align the use of SOFA and qSOFA to further evaluate patients with suspected infection who may be at risk for clinical deterioration. It is important to recognize that not all clinicians will be familiar with the components and use of SOFA. Additionally, because qSOFA has just been introduced as a potential simple bedside scoring tool, ongoing evaluation and dissemination of strategies for integrating use of both qSOFA and SOFA in clinical practice will be required.

As outlined in Sepsis-3, a qSOFA score of 2 or greater should prompt the clinician to assess for evidence of organ system dysfunction (see Figure). The presence of qSOFA criteria should also prompt consideration of possible infection in patients not
Table 2
Surviving Sepsis Campaign bundles

<table>
<thead>
<tr>
<th>To be completed within 3 hours of time of presentation:</th>
<th>(defined as the time of triage in the emergency department or, if presenting from another care area, from the earliest chart annotation consistent with all elements of septic shock ascertained through chart review)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Measure lactate level</td>
<td></td>
</tr>
<tr>
<td>2. Obtain blood cultures before administration of antibiotics</td>
<td></td>
</tr>
<tr>
<td>3. Administer broad-spectrum antibiotics</td>
<td></td>
</tr>
<tr>
<td>4. Administer 30 mL/kg crystalloid for hypotension or lactate ≥ 4 mmol/L</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>To be completed within 6 hours of time of presentation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65 mm Hg</td>
</tr>
<tr>
<td>6. In the event of persistent hypotension after initial fluid administration (MAP ≤ 65 mm Hg) or if initial lactate level was ≥ 4 mmol/L, reassess volume status and tissue perfusion and document findings (reassessment of volume status and tissue perfusion as outlined below)</td>
</tr>
<tr>
<td>7. Remeasure lactate level if initial lactate level is elevated</td>
</tr>
</tbody>
</table>

Document reassessment of volume status and tissue perfusion with

EITHER:

- Repeat focused examination (after initial fluid resuscitation), including vital signs, cardiopulmonary, capillary refill, pulse, and skin findings

OR TWO OF THE FOLLOWING:

- Measure central venous pressure
- Measure central venous oxygen saturation
- Bedside cardiovascular ultrasound
- Dynamic assessment of fluid responsiveness with passive leg raise or fluid challenge

*Based on information from the Surviving Sepsis Campaign website (http://www.survivingsepsis.org/bundles/Pages/default.aspx).*

Previously thought to have an infection.11 If the SOFA score is 2 or less, the patient should still be evaluated for possible sepsis (ie, organ dysfunction) if clinically concerned (eg, oliguria, hypoxemia); if not, his or her clinical condition should be monitored with reevaluation as necessary.11 If there is a change in a SOFA score of 2 or greater that is related to the suspected infection, the patient fulfills the criteria for sepsis; however, this diagnosis may need subsequent amendment if the suspected infection turns out to be another condition such as pancreatitis or a drug reaction.

The presence of 2 or more SOFA points should prompt clinicians to evaluate the patient further for the presence of infection and/or organ dysfunction, to start or adapt treatment, and to consider transfer to an ICU.11 The SOFA score, in itself, is not within the definition but rather is a clinical descriptor of patients fulfilling the new definition of sepsis, namely, organ dysfunction related to an infection. Additionally, SOFA is not intended to replace SIRS.33 Sepsis-3 clarifies that SIRS criteria may still remain useful for the identification of infection (eg, changes in body temperature, white blood cell count) but not for organ dysfunction.11 Currently, many screening protocols and tools used in emergency departments, by rapid response teams, and for hospital inpatients integrate use of the SIRS criteria. Methods to incorporate the new sepsis definitions along with current screening tools used in clinical practice will require continued evaluation.

Improving management of sepsis has been identified as a priority area for patient care. The 2012 SSC guidelines recommend screening for sepsis and implementation of a hospital-based performance improvement program.14 Sepsis has gained governmental agency interest in the United States, whereby hospitals are currently focused on a quality measure to improve sepsis recognition and management as part of a Centers for Medicare and Medicaid Services (CMS) requirement. CMS has designated care for patients with sepsis and septic shock as an area for outpatient quality reporting. The measure centered on early recognition of sepsis and prompt initiation of treatment coupled with a follow-up evaluation of the adequacy of treatment.35,36 Data collection of the Severe Sepsis and Septic Shock Management Bundle measure (SEP-1) began with discharges on or after October 1, 2015. The measure was adopted for the fiscal year 2017 payment determination in the calendar year 2015 Inpatient Prospective Payment System final rule. The SEP-1 measure focuses on patients aged 18 years and older who have symptoms of severe sepsis or septic shock, with the recommendation that the 3-hour and 6-hour sepsis bundles be implemented.15 Adopting and integrating the new definitions may take time as governing bodies such as CMS and third-party payers continue to use previous modified definitions for sepsis and septic shock. Important to clinical practice is early identification and treatment, which is the core of all sepsis definitions and performance improvement initiatives. How quickly sepsis is identified in the clinical setting is crucial in improving patient care.

The sepsis bundles, as outlined as part of the SSC, remain a cornerstone of sepsis treatment (Table 2). Integration of Sepsis-3 into the SSC guidelines may
help in promoting clinical application and use of the new definitions. Importantly, the now clearly specified clinical criteria used to describe patients with sepsis and septic shock should lead to improvements in consistency of reporting, coding, epidemiology, and research. The overlap between infection and sepsis and between sepsis and severe sepsis has been too great, and it has been unclear what constitutes “septic shock.”

The new definitions affect clinical care for sepsis identification, as the terms severe sepsis and systemic inflammatory response syndrome (SIRS) criteria are no longer used in Sepsis-3. In evaluating adoption of the Sepsis-3 definitions, institutions will need to evaluate how changes are needed to identify patients with sepsis (eg, from use of SIRS criteria to an organ dysfunction–based system) and whether other processes need to be instituted (eg, implementing use of SOFA and qSOFA).

Using sepsis as a performance improvement opportunity to enhance clinical recognition and management of sepsis remains a priority. In tracking metrics such as time to measurement of lactate levels, time to collection of samples for blood cultures, time to administration of antibiotics, and other quality goals, individual institutions can improve sepsis care and outcomes. Using the new clinical criteria in Sepsis-3, for example, tracking use of SOFA or qSOFA, to evaluate possible additional sepsis-related metrics further may also be helpful.

**Conclusions**

The new definitions and clinical criteria are aimed at providing a standardized classification to facilitate clinical care, future research, and reporting. Integrating the new sepsis definitions will require clinicians to evaluate how the new definitions will be incorporated into practice in the current landscape of sepsis measures and coding processes. Uncertainty about how the new definitions will be assimilated into existing reporting measures, including CMS metrics and payers, will require continued dialogue. Although the validity of the new clinical criteria for identifying patients with suspected infection who are at risk for sepsis was established to support the use of new components of the definition work, such as qSOFA, additional validation and clinical use will be required. Prospective validation to determine the real-world performance of Sepsis-3 would be beneficial to clinicians and researchers.

The ultimate aim of refining definitions, updating clinical practice guidelines, and advancing research on novel therapeutic options is to improve outcomes for patients with sepsis. As the critical care community further establishes the clinical utility of Sepsis-3, it will be important that examples of clinical application, exemplars of integration into reporting metrics, and use in clinical trial work be widely disseminated in order to maximize benefit for critically ill patients.

**DISCLOSURES**

Robert Balk served on the task force to develop the American College of Chest Physicians–Society of Critical Care Medicine Consensus Conference definitions of sepsis and participated in the second international sepsis definitions conference; Ruth Kleinpell and Christa Schorr serve on the Surviving Sepsis Campaign Guidelines committee; Christa Schorr has conducted research using the Surviving Sepsis Campaign database; Ruth Kleinpell serves on the council board of the Society of Critical Care Medicine, a co-convenor organization along with the European Society of Intensive Care Medicine, of the Surviving Sepsis Campaign Guidelines.

**REFERENCES**


**ECG Puzzler**

A regular feature of the *American Journal of Critical Care*, the ECG Puzzler addresses electrocardiogram (ECG) interpretation for clinical practice. To send an eLetter or to contribute to an online discussion about this article, visit www.ajcconline.org and click “Respond to This Article” on either the full-text or PDF view of the article. We welcome letters regarding this feature.

### Repolarization Alterations in a Genetic Disorder

By Teri M. Kozik, RN, PhD, CNS, CCRN, Mary G. Carey, RN, PhD, Salah S. Al-Zaiti, RN, PhD, CRNP, and Michele M. Pelter, RN, PhD

**Scenario:** This 12-lead electrocardiogram (ECG) is from a 53-year-old Asian man who came to the emergency department (ED). He had just finished landscaping work on an extremely hot day when he had dizziness and complained of feeling like he was going to pass out. The patient had never experienced this before, so he called 911. In the ambulance, his blood pressure was 98/67 mm Hg, heart rate 95 beats/min, and his temperature was 100.1°F. A liter of intravenous fluids was administered to treat dehydration and lower his body temperature. He was otherwise healthy and not taking any medications.

**Interpretation Questions:**

1. Is the ECG properly calibrated (10 mm) and are leads properly placed?  
   - Yes  
   - No  
   - NA

2. Is this a sinus rhythm (one P wave preceding every QRS complex)?  
   - Yes  
   - No  
   - NA

3. Is the heart rate (R-R interval) normal (60-100/min)?  
   - Yes  
   - No  
   - NA

4. Is the QRS complex narrow (duration < 110 milliseconds [ms] in V1)?  
   - Yes  
   - No  
   - NA

5. Is the ST segment deviated (> 2 mm in V2-V3, or > 1 mm in other leads)?  
   - Yes  
   - No  
   - NA

6. Is the T wave inverted in relation to the QRS (> 0.5 mV)?  
   - Yes  
   - No  
   - NA

7. Is the QT interval lengthened (> 450 ms [men] or > 470 ms [women])?  
   - Yes  
   - No  
   - NA

8. Is R- or S-wave amplitude enlarged (S wave V1 + R wave V5 > 35 mm)?  
   - Yes  
   - No  
   - NA

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Teri M. Kozik is a nurse researcher at St. Joseph’s Medical Center, Stockton, California. Mary G. Carey is associate director for clinical nursing research, Strong Memorial Hospital, Rochester, New York. Salah S. Al-Zaiti is an assistant professor at the Department of Acute and Tertiary Care Nursing, University of Pittsburgh, Pennsylvania. Michele M. Pelter is an assistant professor at the the Department of Physiological Nursing at University of California, San Francisco, California.

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Interpretation

On ED admission, the ECG showed sinus bradycardia with ST segment changes in the septal precordial leads resembling features of Brugada syndrome (BrS).

Rationale

Brugada syndrome is a genetic arrhythmic disorder caused by cardiac sodium-channel mutations. Patients with BrS are at risk for sudden cardiac death from ventricular fibrillation (VF); however, most will be asymptomatic throughout their lives. Syncope is one of the most common symptoms in those who seek medical care. Unfortunately, some patients experience sudden cardiac death due to VF. The mean age range of patients with VF due to BrS is 41 to 56 years, occurring more often in men; however BrS arrhythmic events can occur in infancy, and this disorder is now recognized as a cause of sudden infant death syndrome. BrS is more prevalent among the Asian population. Arrhythmic events from BrS occur most often at rest, while asleep, or during febrile states. BrS can be classified into 3 types based on the ST elevation pattern in V1 and V2. Type 1 exhibits a coved type of ST-elevation of ≥2mm at the peak followed by a negative T wave, which is congruent with the discharge ECG (arrows). In Type 2, V1 and V2 exhibit a saddleback type of ST-elevation and J-wave amplitude of ≥2mm; in addition, the ST-elevation remains ≥1mm above the baseline, which is congruent with his initial ECG (arrows). Type 3 BrS exhibits a saddleback type of ST-elevation. Type 1 is the hallmark for patients with BrS but these ECG features are not always present. Interestingly, patients can alternate between ECG BrS types as seen in this example. This patient arrived with Type 2 and spontaneously converted to Type 1 before hospital discharge.

Management

Patients with Type 2 or Type 3 ECG patterns require an intravenous sodium channel blocker drug challenge. This test will unmask a true BrS by conversion to a Type 1 ST-T wave ECG pattern for a definitive diagnosis. Those with symptoms and Type 1 BrS are at risk for future arrhythmic events. An implantable cardioverter defibrillator (ICD) may be indicated in patients with symptomatic BrS (ie, ventricular tachycardia, VF, or syncope associated with a malignant arrhythmia). Asymptomatic patients have a low rate of arrhythmic events and a high complication rate with ICD implantation, therefore, this group should be carefully assessed by an electrophysiologist to determine if treatment with an antiarrhythmic medication such as quinidine is warranted. This patient was discharged home and referred to an electrophysiologist who later implanted an ICD.

REFERENCES

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*Contact:* Laura Tobin.  
*Phone:* (916) 781-1651.  
*E-mail:* Tobs4@hotmail.com.  
*Fee:* $150.

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*Contact:* Kristen Mulholand.  
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*Place:* Nova Southeastern University.  
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*Keynote Speaker:* Kendra Menzies Kent.  
*Sponsor:* Greater Miami Area Chapter of AACN.  
*Contact:* Ruth Salathe.  
*Phone:* (305) 586-4203.  
*E-mail:* ruthsalathe@gmail.com.  
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*Sponsor:* Region 6.  
*Contact:* Tammy Carter.  
*Phone:* (706) 564-2015.  
*E-mail:* tcarter1@augusta.edu.  
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*Sponsor:* Greater Louisville Chapter of AACN.  
*Contact:* Deb Tuggle.  
*Phone:* (502) 500-5010.  
*E-mail:* deborahjtuggle@gmail.com.  
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### Maryland

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*Sponsor:* Chesapeake Bay Chapter of AACN.  
*Contact:* Jean Little.  
*Phone:* (410) 353-2607.  
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